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INCREASING ACCESS TO EMERGENCY CONTRACEPTIVE PILLS THROUGH STATE LAW ENABLED DEPENDENT PHARMACIST PRESCRIBERS

Heather M. Field*

ABSTRACT

Emergency contraceptive pills (“ECPs”), a form of contraception which has a 75% chance of preventing pregnancy when taken within 72 hours after unprotected intercourse, are currently available only by prescription. Increasing access to ECPs will help to reduce unintended pregnancies and abortions and will help to provide women with an extra level of control over their reproductive futures. Private access initiatives, while helpful, are insufficient to address the access problem; federal level solutions are unlikely to be implemented soon. Thus, this Article proposes that all states adopt the Washington model for dependent pharmacist prescribers, whereby state law enables physicians to create collaborative agreements with pharmacists, pursuant to which the physician can effectively delegate to a pharmacist in a retail setting the power to prescribe ECPs. Dependent pharmacist prescribing of ECPs increases access to contraception, increases patient satisfaction and decreasing cost, while preserving patient safety through screening mechanisms and the good safety profile of ECPs. A state-by-state analysis of pharmacy law reveals that while there is a national trend expanding the scope of pharmacy practice, states vary widely in the amount of prescribing power allowed to pharmacists. However, dependent pharmacist prescribing of ECPs is currently feasible in a few states and close in a number of others, and implementation of dependent pharmacist prescribing in some states may lead to greater nationwide acceptance of both dependent pharmacist prescribing and of ECPs.

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I. INTRODUCTION

Every year, there are more than three million unintended pregnancies in the United States, resulting in over 1.4 million abortions. Emergency contraceptive pills ("ECPs") could drastically reduce unintended pregnancies and abortions. ECPs are a form of contraception that has a 75% chance of preventing pregnancy when taken within seventy-two hours of unprotected intercourse. If access to ECPs is increased, women could have an extra level of control over their reproductive futures, deciding whether and when to have children. While oral contraceptives ("OCs") have been used for years to provide emergency contraception, it is only recently that ECP products have become available specifically for that purpose. Unfortunately, those products are available through prescription only. Therefore, obtaining ECPs can be a time-consuming process for women. With an increase in the amount of time between unprotected intercourse and the beginning of the ECP regime, the efficacy of ECPs decreases sharply. Thus, ECPs are not widely used and fail to reach their potential impact on reducing unintended pregnancies and on increasing women's control over their reproductive futures.

This paper proposes that access to ECPs should be increased by making ECP prescriptions available through dependent pharmacist prescribers. Since the Federal Food, Drug, and Cosmetic Act ("FDCA") defers to state law in the determination of which health care providers may exercise prescriptive authority, states should allow pharmacists to prescribe ECPs. Specifically, pharmacists could create collaborative agreements with health care practitioners to allow pharmacists in retail settings to exercise dependent prescriptive authority.

Dependent pharmacist prescribing, as proposed in this paper, is an expansion of the pharmacist's traditional role of dispensing drugs.¹ The authority for pharmacists is described as "dependent" because the pharmacist depends on delegated prescriptive authority from a supervising practitioner with whom the pharmacist has collaborated to create a protocol for the prescriptive authority and procedure.² A professional who prescribes dependently receives delegated authority from an independent

1. Although the role of the pharmacist has been expanding in recent years, the traditional role of pharmacists does not include any type of prescriptive authority.

2. See Kimberly A. Galt, *The Key to Pharmacist Prescribing: Collaboration*, 52 AM. J. HEALTH-SYS. PHARMACY 1696, 1696 (1995). The dependent pharmacist prescriptive authority proposed in this paper is modeled after the Washington state

prescriber, thus "dependent authority implies shared responsibility based on the premise that the physician who delegates prescribing privileges is confident in the professional judgment and skill level of the individual receiving the delegated authority."³ Thus, by allowing physicians to collaborate with pharmacists in order to delegate the authority to prescribe ECPs pursuant to a collaborative protocol, access to ECPs can be increased because women will be able to obtain prescriptions for ECPs from their local dependent pharmacist prescribers.

This paper discusses the current level of access to ECPs, evaluates the arguments surrounding the potential solutions to increasing access to ECPs, and provides examples of how dependent pharmacist prescribing may be successfully implemented. Specifically, the problem of available access to ECPs and the current initiatives to increase access to ECPs that have been taken in the United States and around the world are discussed in Part II. Part III addresses the traditional arguments against pharmacist prescribers and explains why dependent pharmacist prescribers are a good solution to the problem of ECP access. Additionally, Part III discusses why potential federal-level solutions to the ECP access problem are unlikely to occur, and discusses how state-based dependent pharmacist prescribing fits into the federal schemes for prescription and nonprescription drugs. Finally, Part IV of this paper provides a model of how some states have successfully moved towards dependent pharmacist prescribing in order to increase access to ECPs. Part IV also offers a brief evaluation of whether pharmacists in each state can currently or will soon be able to exercise dependent prescriptive authority and thereby prescribe ECPs based on collaborative agreements with practitioners.

This paper concludes that, while dependent pharmacist prescribing of ECPs cannot solve all of the problems of unintended pregnancies and abortions, nor can it by itself empower women to have total control over their reproductive futures, dependent pharmacist prescribing is a prudent option for increasing access to ECPs. The increased access can then help ECPs reach their potential impact to help combat these problems. Additionally, because dependent pharmacist prescribing is currently feasible in a few states and close in a number of others, the resulting in-

pharmacist prescribing regime, details of which are discussed later in this paper. See *infra* Part IV.B.1.a.

3. Galt, *supra* note 2.

creased access in these states may lead to greater nationwide acceptance both of dependent pharmacist prescribing and of ECPs. That acceptance may hasten a move toward more state-based dependent pharmacist prescribers or may provide a more easily acceptable transition of ECPs to over-the-counter (“OTC”) status.

II. THE PROBLEM OF THE CURRENT LEVEL OF ACCESS TO EMERGENCY CONTRACEPTIVE PILLS (“EPSs”)

A. *Introduction to ECPs*

Although most contraception is intended to be used either before or during intercourse, methods for post-coital contraception have been developed over the last thirty years.⁴ A woman has approximately a 75% chance⁵ of preventing pregnancy after unprotected intercourse if she uses “morning-after pills” or “emergency contraceptive pills.”⁶ ECPs are high doses of OCs ingested within a short period of time after intercourse.⁷ The pills, which contain high doses of estrogens and progestins, work to prevent conception.⁸

4. See Charlotte Ellertson, *History and Efficacy of Emergency Contraception: Beyond Coca-Cola*, 28 *FAM. PLAN. PERSP.* 44, 44 (1996). The copper IUD is a common nonhormonal method of emergency contraception. See *id.* However, this paper will focus on a hormonal method involving emergency contraceptive pills.

5. See generally James Trussell et al., *The Effectiveness of the Yuzpe Regimen of Emergency Contraception*, 28 *FAM. PLAN. PERSP.* 58 (1996).

6. The term “morning-after pill” is a misnomer because the pills may be taken as soon as immediately after or as late as 72 hours after unprotected intercourse. See Ellertson, *supra* note 4, at 44. Therefore, for the purposes of this paper, the more accurate term “emergency contraceptive pills” or “ECPs” will be used.

7. See *id.*

8. See Elizabeth Westley, *Emergency Contraception: A Global Overview*, 53 *J. AM. MED. WOMEN’S ASS’N* 215, 216 (1998). Possible mechanisms for ECPs include the inhibition or delaying of ovulation, the “disrupt[ion] of the luteal phase of the cycle,” or the interference with implantation. *Id.*; Anna Glasier, *Drug Therapy: Emergency Postcoital Contraception*, 337 *NEW ENG. J. MED.* 1058, 1059-60 (1997). “Basically, EC pills interrupt the hormonal balance of the menstrual cycle by changing a number of the processes that are [naturally] occurring . . .” *Emergency Contraception: Preparing for Increased Patient Demand: An Interview with Susan Wysocki*, 8 *CLINICIAN REVS.* 53, ¶7 (1998) (visited Dec. 19, 2000) <<http://www.medscape.com/CPG/ClinReviews/1998/v08.n11/c0811.01/pnt-c0811.01.html>>. ECPs differ from mifepristone (commonly referred to as RU-486) which is an abortifacient. See *id.* at ¶12. It is important to note, that despite confusion on the issue, ECPs prevent pregnancy, but do not terminate pregnancies, and therefore emergency contraception is not a form of abortion. See Center for Reproductive Law & Policy, *Emergency Contraception: Contraception, Not Abortion: An Analysis of Laws and Policy Around the World* (Feb. 1999) (visited Dec. 19, 2000) <<http://204.168.19.126/icpdec2.html>>; see also *infra* Part III.B.6.b. (discussing, in the context

Professor A. Albert Yuzpe developed the best-studied method for emergency contraception.⁹ The "Yuzpe method" requires a woman to take two tablets, each containing 0.05 mg of ethinyl estradiol (estrogen) and 0.50 mg of norgestrel (progestin), within seventy-two hours of unprotected intercourse, and to take two more tablets twelve hours later.¹⁰ Many commercially available brands of OCs can provide the hormone doses required under the Yuzpe method.¹¹ The Yuzpe method of emergency contraception is associated with side effects in some women ranging from headaches and breast tenderness to nausea and vomiting.¹² However, the progestin-only variation on the Yuzpe method of emergency contraception tends to have a lower incidence of side effects.¹³

B. *Availability of and Access to ECPs Outside of the United States*

For many years, commercially available OCs have been used to provide Yuzpe method emergency contraception to women in the United States although they were not labeled and marketed for such use. In 1996, the FDA explicitly approved of such use.¹⁴ Since then, one Yuzpe method product, PREVEN,¹⁵ and one progestin-only product, PLAN B,¹⁶ have been made available through prescription in the United States market.

The transition in the United States to dedicated emergency contraception follows broader acceptance of emergency contra-

of conscience clauses, the rationale supporting classification of ECPs as contraception and not abortion).

9. See Ellertson, *supra* note 4, at 44; see also Prescription Drug Products; Certain Combined Oral Contraceptives for Use as Postcoital Emergency Contraception, 62 Fed. Reg. 8609, 8610 (1997) [hereinafter FDA Notice on ECPs].

10. See A.A. Yuzpe et al., *Post Coital Contraception — A Pilot Study*, 13 J. REPROD. MED. 53 (1974).

11. See Westley, *supra* note 8, at 216; see also FDA Notice on ECPs, 62 Fed. Reg. at 8612.

12. See Task Force on Postovulatory Methods of Fertility Regulation: World Health Organization, *Randomised Controlled Trial of Levonorgestrel versus the Yuzpe Regimen of Combined Oral Contraceptives for Emergency Contraception*, 352 LANCET 428, 431 (1998) [hereinafter WHO Task Force on ECPs].

13. See *id.*; Westley, *supra* note 8, at 216.

14. See FDA Notice on ECPs, 62 Fed. Reg. at 8610.

15. See *Preven Emergency Contraception Center* (visited Jan. 16, 1999) <<http://www.preven.com/>>; see also Julian De Bruyn Kops, *FDA Approves Morning-after Pill*, IDAHO FALLS POST REG., Aug. 27, 1999, at D6.

16. See *Consumer's Guide to Plan B* (visited Oct. 19, 1999) <<http://www.go2planb.com/guide/guide.html>>; see also Kim Painter, *Morning-after Pills Easier on the Stomach*, USA TODAY, Aug. 2, 1999, at D8.

ception around the world. ECPs have been available in the United Kingdom since 1984, and in numerous other countries including Germany, Sweden, Switzerland, New Zealand, South Africa, China, Hungary, and Thailand. Some of these countries have moved ahead of the United States by providing easier access to ECPs. For example, in Thailand ECPs have been available without a prescription for twenty years.¹⁷ Norlevo, an ECP produced by HRAPharma, has been available OTC in France since June 1999.¹⁸ Furthermore, the major pharmacy associations in Canada, England, and Scotland support ECP access without a prescription, as long as there is some oversight.¹⁹ England has recently initiated a pilot project whereby women can obtain ECPs from specially trained pharmacists at their local pharmacy without contact or approval from a doctor or family planning clinic.²⁰ While these moves have not been without controversy, there is significant support from doctors, pharmacists, nurses, and women's advocacy groups to provide increased access to ECPs.²¹

C. *The Problems with the Current Level of Access to ECPs in the United States*

The current level of access to ECPs in the United States deprives both individual women and society of the potential benefits of ECPs. Despite the widespread availability of pre-coital

17. See Aphaluck Bhatiasavi, *Contraception — Worries Over Abuse of Morning-after Pill*, BANGKOK POST, Oct. 4 1999.

18. See *Norlevo Contraception Progestative Post Coital* (visited Oct. 31, 1999) <<http://www.esculpe.com/medicament/norlevo.html>>; see also Tim Teeman, *A Counter Argument*, TIMES (London), Sept. 25, 1999.

19. See Chris Thatcher, *Emergency Contraception: the "Appropriate Controls,"* CANADIAN PHARMACEUTICAL J., Aug. 1999, at 10 (Canadian Pharmacy Association and the Society of Obstetricians and Gynecologists of Canada support nonprescription access to ECPs with pharmacist involvement); Bryan Christie, *Morning-after Pill Over the Counter; Prescription Rules May Be Relaxed to Help Curb Unwanted Teenage Pregnancies*, MAIL ON SUNDAY, July 11, 1999, at 22 (Scottish Pharmaceutical General Council explains teenage pregnancy rates could be reduced by allowing for ECP access through pharmacists); *The Pharmacist's Role*, COMMUNITY PHARMACY, July 1999, at 26 (Royal Pharmaceutical Society supports expansion of ECP access to allow for more pharmacist involvement).

20. See Helen Carter, *Morning-after Pill Trial Hailed as Success*, THE GUARDIAN (London), Jan. 8, 2000, at 5; Jenny Hope, *Morning-after Pill on Demand; No Prescription Needed at the Chemist*, DAILY MAIL (London), Jan. 8, 2000, at 2.

21. See, e.g., Anna Glasier & David Baird, *The Effects of Self-Administering Emergency Contraception*, 339 NEW ENG. J. MED 1 (1998); Catriona I. Matheson et al., *Over-the-Counter Emergency Contraception: A Feasible Option*, 15 FAM. PRAC. 38 (1998).

contraception, there remains a significant need for emergency contraception for individual women who may find themselves in one of several different situations. First, ECPs can prevent pregnancies among women "suffer[ing] contraceptive accidents — whether a torn condom, a forgotten diaphragm, or missed pills — by giving them another option."²² Second, many women who do not want to get pregnant have unprotected intercourse, for reasons "including lack of access to family planning services and supplies or fear of side effects of available methods."²³ Third, an obvious group of women in need of ECPs are those who have been raped or otherwise coerced into sex.²⁴ Emergency contraception could benefit all of these women by giving them a second (or first, in many cases) chance to prevent an unwanted pregnancy. The two most widely accepted methods of emergency contraception are ECPs and IUDs, and both are available only through prescription.²⁵

The fact that ECPs are only available with a doctor's prescription presents two significant obstacles for women in need of ECPs — time and money. First, although the ECP regime may be started up to 72 hours after unprotected intercourse, it is most effective when started as soon as possible.²⁶ However, it is generally difficult for a woman to visit her doctor in the evenings, on weekends, or while she is out of town, should unprotected intercourse occur during these times (which it often does). If, in these circumstances, a woman is fortunate enough to be able to see her doctor for a prescription within the seventy-two hour period, there is still an increase in the amount of time before beginning

22. Westley, *supra* note 8, at 215.

23. *Id.* (citing demographic and health surveys about the unmet need for pre-coital contraception).

24. *See id.*

25. *See id.* IUDs (intra-uterine devices) can be inserted post-coitally as an emergency method of contraception, and can thereafter be used as regular ongoing contraception. This paper will not argue that women should have easy access to IUDs without a doctor because IUDs have a longer window for effectiveness than ECPs and, more importantly, because IUD insertion "requires a trained provider and is more risky for women who may have been exposed to sexually transmitted infection." *Id.* at 216. Furthermore, there remain concerns about the safety of IUDs. *See* Centers for Disease Control and Prevention, *Current Trends — IUD Safety: Report of a Nationwide Physician Survey*, 46 MORBIDITY & MORTALITY WKLY. REP. 969 (1997).

26. *See* WHO Task Force on ECPs, *supra* note 12, at 432 (stating that "[f]or both methods combined [progestin-only and estrogen/progestin], efficacy [of the ECP regimen] was significantly and inversely related to time since unprotected coitus").

the ECP regimen (as compared to the time before beginning the regimen if the ECP was immediately available). The effectiveness of the ECP will likely decrease²⁷ during this time and the woman will likely suffer an increase in related anxiety. Second, the need for a doctor's visit costs the woman financially. The cost of the visit itself coupled with the cost of missed time at work can be burdensome for many women. Thus, the cumbersome nature of the ECP prescription process and the financial burden of a doctor's visit and missed work time prevent women who have had unprotected intercourse from having ready access to this simple measure to prevent an unintended pregnancy.

The problem of access to ECPs does not end with the individual women in need of them. Unintended pregnancies, especially those by teenagers, are a major public health problem.²⁸ More than 3 million unintended pregnancies occur every year in the United States, resulting in 1.4 million abortions and 1.2 million mistimed/unwanted births.²⁹ Better access to ECPs could help address this problem. It is estimated that widespread use of emergency post-coital contraception could prevent 1.7 million unintended pregnancies and 0.8 million abortions each year in the United States.³⁰ With greater knowledge about ECPs among women and clinicians, and with enhanced availability, ECPs can

27. *See id.*

28. *See* Centers for Disease Control and Prevention, *Insurance Coverage of Unintended Pregnancies Resulting in Live-Born Infants — Florida, Georgia, Oklahoma, South Carolina, 1996*, 48 MORBIDITY & MORTALITY WKLY. REP. 100 (1999) (collecting information and references regarding unintended pregnancies and their consequences).

Unintended pregnancy can result in adverse health outcomes that affect the mother, infant, and family. . . .

. . . .

To reduce the adverse consequences of unintended pregnancies and to maximize the benefits of periconceptional interventions (e.g., use of folic acid and cessation of alcohol consumption), health-care providers and communities need to collaborate in promoting a social norm in which all pregnancies are planned. Findings from this and other reports suggest that access to health care and timely family-planning services to women in all settings is needed to avoid the medical, social, and economic costs of unintended pregnancy.

Id.

29. *See* Alan Guttmacher Institute, *FACTS IN BRIEF: Contraceptive Use 1998* (visited Oct. 23, 2000) <http://www.agi-usa.org/pubs/ft_contr_use.html>.

30. *See* James Trussell et al., *Emergency Contraceptive Pills: A Simple Proposal to Reduce Unintended Pregnancies*, 24 FAM. PLAN. PERSP. 269, 269-70 (1992).

be a "low-cost and effective means of reducing the large number of unintended pregnancies occurring each year" ³¹

D. *Steps Taken by Private Organizations to Reduce the Barriers to Obtaining an ECP Prescription Fail to Solve the Access Problem Even if Such Steps Are Continued*

1. Private Informational and Educational Initiatives

Although some steps have been taken to reduce the burden of obtaining a doctor's prescription for ECPs, these additional resources are insufficient, in part because women lack information about ECPs. The first issue in increasing ECP access is increasing access to information, since women who are unaware of the option of ECPs cannot take advantage of increased methods of physical access and distribution. The magnitude of the information problem and the marked effect of heightened awareness was demonstrated by a pilot program in a few cities, where there was significant affirmative publicity surrounding the launching of the ECP hotline, 1-888-NOT-2-LATE.³² The hotline received substantially more phone calls from women in the target cities as compared to the number of phone calls from women in the nontargeted cities.³³ Although the ECP needs of the target cities and nontarget cities may be somewhat different, certainly some of this substantial increase in ECP awareness and use is attributable to women having more information about ECPs as a second chance to prevent an unintended pregnancy.³⁴ For ECPs to have their maximum potential effect on a woman's ability to control her reproductive future and on the reduction of unintended pregnancies, all women (and men) must know of the option.

However, an educational campaign to heighten awareness about ECPs is insufficient to enable women in need of ECPs to actually be able to use them. There must be a corresponding physical increase in the methods through which women can access ECPs. Knowledge alone will not solve the problems of too few prescribers, too few dispensing facilities, and limited access

31. *Id.* at 273.

32. See James Trussell et al., *Call 1-888-NOT-2-LATE: Promoting Emergency Contraception in the United States*, 53 J. AM. MED. WOMEN'S ASS'N 247, 247 (1998) (discussing the publicity campaign program); see also *infra* Part II.D.2 (discussing the hotline itself).

33. See Trussell et al., *supra* note 32, at 249.

34. See *id.*

to prescribing/dispensing services on evenings, weekends, and during travel. An educational campaign coupled with increased methods of physical access is likely to have a great impact on access to and use of ECPs. Supporting a move toward making ECPs even more readily accessible, such as from a pharmacist,³⁵ likely will generate discussion around this increase in physical access to ECPs and may itself give rise to greater awareness.³⁶

2. Private Access Initiatives

In addition to educational initiatives, numerous steps to increase physical access to ECPs have been taken by private organizations. However, these steps, while moving in the right direction, are still insufficient to meet either the needs of individual women or the needs of society as a whole.

In 1996, Reproductive Health Technologies Project and Bridging the Gap Foundation, Inc. set up a national emergency contraception hotline (1-888-NOT-2-LATE) to provide callers with information about emergency contraception and to provide referrals to local physicians and clinics willing to prescribe ECPs.³⁷ However, too few women know of its existence.³⁸ Additionally, depending on the political climate of the woman's local area, there may not be an ECP prescriber available nearby.³⁹ Furthermore, even if a woman obtains a referral to local doctors/clinics, obtaining ECP prescriptions is still difficult, costly, and time-consuming because many of these doctors/clinics are only available during regular working hours. Also, many of these doctors/clinics may have been reluctant to prescribe ECPs due to their (until recently) off-label status.

35. I will argue in Part III of this paper that ECPs should be available through dependent pharmacist prescriptions.

36. Certainly dependent pharmacist prescribing alone cannot solve the educational/informational problem. Information is a problem with every method of increasing access. However, when coupled with publicity campaigns, dependent pharmacist prescribing can have a significant impact on both awareness and access, improving both beyond their current levels.

37. See NOT-2-LATE.com: The Emergency Contraception Website, *Women Can Prevent Pregnancy After Unprotected Sex: New Toll-Free Hotline to Explain How* (visited Oct. 23, 2000) <<http://ec.princeton.edu/news/hotline.html>>.

38. See Trussell et al., *supra* note 32 (discussing the effect of publicity campaigns on the number of calls placed to the hotline); see also *supra* Part II.D.1 (discussing women's lack of information about ECPs).

39. Dependent pharmacist prescribers could increase the number of ECP prescribers and could therefore increase the likelihood that a woman will be able to access a prescriber close to home. See *infra* Part III.B.1. (discussing how dependent pharmacist prescribers increase access to reproductive care).

Planned Parenthood Federation of America has pioneered another resource to increase access to ECPs; the "Dial EC" service enables "first-time and established patients to receive a prescription for ECPs, and instructions in their use, over the telephone, with no clinic visit required."⁴⁰ If Planned Parenthood clinicians can prescribe ECPs over the phone to women without their medical history on file at the clinic, there are certainly many other health care professionals (like pharmacists and nurses), who could provide similar telephone prescriptions and instructions. Although the "Dial EC" program is helpful, again women may lack information about this option. Women may also obtain ECPs through Planned Parenthood clinic visits, but there are just not enough clinics to physically serve all women in need of ECPs.⁴¹ Rather than trying to alleviate the problem of ECP access by opening more clinics, ECP access can be increased more efficiently through dependent pharmacist prescribing which takes advantage of the pharmacy distribution network that is already established.

Another option available to women is to order ECPs over the Internet. Although clearly illegal according to the recent Clinton Administration and FDA Initiative to protect consumers buying prescription drug products over the Internet,⁴² women can obtain ECPs through Internet pharmacies that will ship the ECPs overnight by merely filling out a medical questionnaire.⁴³ Internet prescribing is illegal because it eliminates safeguards for

40. Planned Parenthood Federation of America, *Fact Sheet: Emergency Hormonal Contraception: A Short History* (last modified Sept. 1998) <<http://www.plannedparenthood.org/library/BIRTHCONTROL/EmergContraHistory.htm>> [hereinafter Planned Parenthood ECP History]. Planned Parenthood also has another new service, "EC-to-Go," which "offers women ECP kits to take home 'just in case.'" *Id.*

41. There are only approximately 875 Planned Parenthood centers throughout the United States. Planned Parenthood Federation of America, *This is Planned Parenthood* (visited Oct. 23, 2000) <<http://plannedparenthood.org/ABOUT/thisispp/default.html>>.

42. See Office of The Press Secretary, White House, *The Clinton Administration Unveils New Initiative to Protect Consumers Buying Prescription Drug Products Over the Internet* (released Dec. 28, 1999) <<http://www.fda.gov/oc/buyonline/onlinesalespr.html>> [hereinafter Internet Prescription Initiative].

43. See, e.g., OSI Medical Services, *SafeWeb Medical: Preven Consultations and Prescriptions* (visited Oct. 23, 2000) <<http://www.safewebmedical.com/preven.html>> (providing ECP prescription and next day delivery after completing a short questionnaire about medical history and agreeing to a waiver).

protecting consumers from unsafe drugs.⁴⁴ New federal budget funds are being allocated to “crack down” on this problem, and thus ECPs are unlikely to be available through this Internet prescribing method for much longer.⁴⁵ This method of increasing access (even if continued) is also distributionally inequitable. Internet ECP access does not help disadvantaged women, who may benefit the most from easy ECP access, because those women are unlikely to have computers, have credit cards, or be able to pay the significantly higher prices required for Internet ordering and express delivery.

Some legal attempts have been made to make use of the Internet for improving ECP access. Many groups have posted information on the Internet about how to use OCs as ECPs, thereby enabling women to self-medicate.⁴⁶ While this is another good step toward empowering women, this information, again, helps only those women with computer/Internet access, knowledge that OCs can be used somehow as ECPs, and who already have OCs at home.

Steps are also being taken to combat some of the time constraints related to efficacy of ECPs. Since these problems are ex-

44. See Internet Prescription Initiative, *supra* note 42; see also *infra* Part III.D.2 (discussing the federal requirements for valid prescriptions as informed by federal case law and by this Internet prescription initiative).

45. The Internet Prescription Initiative provides for \$10 million to be included in the year 2001 budget. See Internet Prescription Initiative, *supra* note 42, ¶1. This money is in part to fund “making Internet monitoring [of drug prescribing activity] a higher priority and taking criminal or civil actions if needed.” *On-line Sales of Prescription Drugs to Get Closer Scrutiny*, FDA CONSUMER, Nov.-Dec. 1999, at 3. Furthermore, the initiative would

establish new Federal requirements for all Internet pharmacies to ensure that they comply with state and Federal laws; create new civil penalties for the illegal sale of pharmaceuticals; give Federal agencies new authority to swiftly gather the information needed to prosecute offenders; expand Federal enforcement efforts; and launch a new public education campaign about the potential dangers of buying prescription drugs online.

Internet Prescription Initiative, *supra* note 42, at ¶ 1.

46. See, e.g., Planned Parenthood Federation of America, *Fact Sheet: Emergency Contraception* (last modified July 2000) <<http://www.plannedparenthood.org/library/BIRTHCONTROL/EmergContra.htm>> (containing directions for ECP use and a chart explaining how many pills to take for each dose of the ECP regime based on the underlying oral contraceptive brand) [hereinafter Planned Parenthood ECP Fact Sheet]; Feminist Women’s Health Center, *Emergency Contraception* (visited Oct. 23, 2000) <<http://www.fwhc.org/ecinfo.html>> (same); NOT-2-LATE.com: The Emergency Contraception Website, *Brands of Oral Contraceptives that Can Be Used for Emergency Contraception in the United States* (visited Oct. 23, 2000) <<http://ec.princeton.edu/questions/dose.html>> (same).

acerbated by the requirement of obtaining a physician's prescription, some doctors and clinics are moving toward prescribing ECPs in advance and allowing women to keep them at home for use as needed.⁴⁷ This significantly improves access and improves control over reproduction for women whose physicians are willing to provide an advance prescription. This move demonstrates a well-deserved trust in women to be able to self-diagnose and to self-administer correctly.⁴⁸ While this move toward advance prescription of ECPs is helpful and should be encouraged until better methods of easy access are implemented, there are a number of drawbacks to this approach. First, this only helps women whose physicians are willing to provide an advance prescription. Many physicians may not be so willing. Second, for those women who can obtain an advance prescription, many may not want to incur the expense of purchasing an advance supply of ECPs not knowing whether they will ever need them. However, this problem with advance prescriptions may be alleviated if the prescription can be filled at a significantly later date than when it was written. Then women could choose to fill the prescription and incur the cost only when there is a need for the ECP.

While providing widespread advance prescriptions to be filled when needed seems like a good solution, an affirmative stance on ECPs by state or federal governments is preferable, lest politicians sidestep the issue by allowing private parties to circumvent the political process by working around the current regime. Such an abdication of power to individual doctors or private foundations prevents political accountability and may lead to arbitrary results because implicit delegation of the method of prescription/dispensation of ECPs to private parties fails to ensure fair treatment to all women.

47. See Center for Reproductive Law & Policy, *Emergency Contraceptive Pills: Common Legal Questions About Prescribing, Dispensing, Repackaging, and Advertising* ¶ 6 (visited Oct. 19, 1999) <<http://www.crlp.org/1997ecp.html>>; Planned Parenthood ECP History, *supra* note 40 (discussing Planned Parenthood's "EC-to-Go" program). It should be noted, that ECPs, like all other drugs, have limited shelf lives. Expiration dates should be on the packages.

48. See Glasier & Baird, *supra* note 21 (finding that women who were given ECPs to keep at home self-diagnosed and self-administered correctly and responsibly).

III. PROPOSED SOLUTION: ALLOW PHARMACISTS TO
DEPENDENTLY PRESCRIBE ECPs BASED
ON COLLABORATIVE PROTOCOLS
WITH PHYSICIANS

The most feasible way to increase access to ECPs is to modify state pharmacy law to allow pharmacists who collaborate with physicians to be classified as “dependent” practitioners for the purposes of prescribing and dispensing ECPs[,] and to include in the definition of the practice of pharmacy the ability to prescribe in accordance with a collaborative protocol.⁴⁹ Each state should follow the lead set by the state of Washington and allow pharmacists to create collaborative agreements with physicians, which would enable pharmacists in retail settings to prescribe ECPs, for requesting women in accordance with a protocol approved by state administrators.⁵⁰ Thus, most women should be enabled to obtain an ECP prescription and the ECPs themselves at the same time from their local dependent pharmacist prescriber.

A. *Introduction to the Process for Dependent Pharmacist Prescribing of ECPs*

Under the dependent pharmacist prescribing model, physicians and pharmacists would agree to an ECP collaborative

49. It is important to note that this proposal does not advocate for the creation of a *nonprescription* drug available from pharmacists only. Instead, the proposal advocates maintaining prescription status for ECPs, but broadening the state law definition of “practitioner” to include pharmacists collaborating with physicians. This dependent pharmacist prescribing power would coexist with physician prescribing power for ECPs. This distinction is very important in order to prevent possible federal preemption and in order to provide a framework for understanding the possible federal-level alternatives. See *infra* Part III.D.1. (discussing preemption); *infra* Part III.C. (discussing federal alternatives).

50. This proposal is modeled after the Washington State Pilot Project with the Program for Appropriate Technology in Health (“PATH”). See Elisa S. Wells et al., *Investigation of Use of Pharmacist Prescriptive Protocols for Emergency Contraceptive Pills (ECPs): Final Report to the David and Lucile Packard Foundation* (May 30, 1997) (on file with Program for Appropriate Technology in Health, Seattle, Wash. (“PATH”)) [hereinafter *Final PATH Report*]; see also Elisa S. Wells et al., *Using Pharmacies in Washington State to Expand Access to Emergency Contraception*, 30 *FAM. PLAN. PERSP.* 288 (1998) [hereinafter *Wells et al., Using Pharmacies*]. It is important to note that the pharmacists involved in this program need not practice in institutional settings; in fact, dependent pharmacist prescribing of ECPs will be much more effective if retail pharmacists exercise the authority. Additionally, this model does not require or even prefer that the requesting woman have a doctor-patient relationship with the collaborating physician. See *infra* Part IV.B.1.a. (discussing the Washington dependent pharmacist prescriber plan and its characteristics in detail).

agreement under which a physician effectively delegates some of his prescribing authority to the pharmacist. This authority is to be used by the pharmacist to prescribe ECPs in accordance with the guidelines set forth in the collaborative agreement or protocol.⁵¹ The protocol is intended to ensure that the patient receives information necessary to effectively and safely complete the ECP treatment.⁵² The agreement may also establish training requirements for the pharmacist and establish a reporting procedure between the pharmacist and physician to ensure adequate checks on the pharmacist.⁵³

An example of the process of dependent pharmacist prescription of ECPs is as follows: If a woman requests ECPs, the dependent pharmacist prescriber will refer to the protocol established with the collaborating physician in order to determine whether an ECP prescription would be safe and appropriate for the requesting woman. Under a standard protocol, a dependent pharmacist prescriber will only prescribe the ECPs if it has been less than 72 hours since the unprotected intercourse, if the unprotected intercourse was the sole risk episode in the cycle (or if there were multiple risk episodes, only if the initial risk episode was less than 72 hours prior), if the woman's last period was normal and on time, if the woman's last period was less than 31 days prior (to rule out established pregnancy); and if the woman does not have a history of the more serious risk factors for OCs.⁵⁴ Women who do not meet these criteria will be referred to a phy-

51. Again, this proposal is modeled after the Washington State Pilot Project with PATH. See Final PATH Report, *supra* note 50.

52. See Program for Appropriate Technology in Health, ECP Collaborative Agreement Protocol (Sept. 1998) (on file with PATH) (providing a sample collaborative agreement for ECPs) [hereinafter PATH, ECP Collaborative Agreement].

53. See *id.*

54. *Id.*; Matheson et al., *supra* note 21, at 40 (providing a sample pharmacist checklist for the prescribing and dispensing of ECPs).

Although women with risk factors for OCs can safely use ECPs, screening for these factors is a precautionary measure. See *infra* Part III.B.5.b. (discussing risk factors and safety concerns posed by ECPs); *infra* Part III.B.5.c. (discussing screening). Women with a history of blood clots, stroke, heart attack, liver disease, migraines, heavy smoking (among older women), or other major risk factors for OCs may be referred to a physician in accordance with the guidelines established by the protocol. See *infra* Part III.B.5.b.

The dependent pharmacist prescriber should either have a woman complete a medical history questionnaire or should take the written medical history himself. The woman should be asked to sign the history to assure that it is complete and accurate, and the pharmacist should review the medical history with the requesting woman in order to evaluate whether the woman is an appropriate candidate for an ECP prescription written by the dependent pharmacist prescriber.

sician.⁵⁵ The pharmacist will also inquire into general health characteristics of the patient including age, smoking, other drugs taken concurrently, allergies, etc. If the pharmacist determines that an ECP prescription would be safe and appropriate, the dependent pharmacist prescriber may prescribe ECPs and dispense them to the patient. The pharmacist would also consult with the woman about proper administration of the ECP regimen, inform the woman about side effects, recommend that the woman see her regular physician for follow-up, and encourage the woman to consider options for ongoing pre-coital contraception.⁵⁶ The woman must sign an informed consent form for the ECP prescription that provides, among other things, that the pharmacist has explained to her the pros and cons of ECPs and that she acknowledges that she should consult her physician in certain specified circumstances, for example, if her period does not begin within 3 weeks of the treatment or if she is concerned about sexually transmitted diseases.⁵⁷ The pharmacist may provide the patient with informational material about ECPs and contraception to take home with her.⁵⁸ The pharmacist will keep patient medical histories and informed consents in his records for review by the collaborating physician on a previously determined time schedule.

B. *Proposed Solution: Why Dependent Pharmacist Prescribing Is the Right Answer for Increasing Access to ECPs*

Allowing pharmacists to dependently prescribe ECPs enables women to have better control over their reproductive futures, and furthers the public policy goals of reducing abortions and unwanted pregnancies. Together with a public education campaign to raise awareness about the option of ECPs, state expansion of ECP prescribing rights will increase access to, increase the quality of, and decrease the cost of reproductive health care while protecting patients and avoiding many of the concerns related to broader pharmacist prescribing power.

55. See PATH, ECP Collaborative Agreement, *supra* note 52; Matheson et al., *supra* note 21, at 40 (providing a sample pharmacist checklist for the prescribing and dispensing of ECPs).

56. See sources cited *supra* note 55.

57. Program for Appropriate Technology in Health, Informed Consent for Emergency Contraception (Sept. 1998) (on file with PATH).

58. See Final PATH Report, *supra* note 50.

1. Dependent Pharmacist Prescribing of ECPs Increases Access to Reproductive Health Care

Surveyed doctors and pharmacists agree that if a treatment is available through dependent pharmacist prescribers, rather than through a doctor's visit alone, access and convenience for individuals seeking such treatment is increased.⁵⁹ In fact, the Florida law allowing pharmacists to independently prescribe drugs listed on a formulary was passed in part to address the unmet medical needs of the public caused by "patients [having] limited access to the traditional health-care system because it was inconvenient or simply unavailable"⁶⁰ Although some dismiss the benefits of increased access to care and, instead, argue that the issue of primary concern should be patient safety,⁶¹ in the context of ECPs access and safety goals can be targeted simultaneously. Since ECPs have a good safety profile and increased access is unlikely to lead to major adverse drug events,⁶² access must be a central consideration with ECPs, especially because time is the critical factor in the efficacy of the individual ECP treatments and because availability is key to large scale prevention of unwanted pregnancies.

Allowing pharmacists to dependently prescribe ECPs provides, as one of its primary benefits, increased access and convenience for women in need of ECPs.⁶³ If a woman can obtain ECPs easily and quickly, she is much more likely to be able to initiate the treatment within the limited seventy-two hour win-

59. See Tim S. Fuller et al., *Satisfaction with Prescriptive Authority Protocols: How Well Have Protocol Practice Arrangements Between Pharmacists and Physicians Worked for Prescribers in Washington State?*, NS36 J. AM. PHARMACEUTICAL ASS'N 739, 743-45 (1996) (surveying physicians and pharmacists about the impact of prescriptive authority for pharmacists on a variety of issues including patient convenience and access); Radhika Desikan et al., *Prescribing Authority: An Examination of Ohio Pharmacists' Opinions*, AM. PHARMACY, Oct. 1995, at 19, 20.

60. Paul L. Doering, *Pharmacists as Prescribers: The Florida Experience*, 20 DRUG INTELLIGENCE & CLINICAL PHARMACY 983, 984 (1986). Pharmacists in Florida can independently prescribe drugs listed on a limited formulary. See *infra* Part IV.B.2 (describing Florida law). While this prescriptive power is "independent" in that it is not based on any agreement/collaboration with or delegation from a physician, the same benefits of increased access derived from independent prescribing of certain drugs are relevant in the dependent pharmacist prescribing regime for ECPs proposed in this paper.

61. See Phyllis Coleman & Ronald A. Shellow, *Extending Physician's Standard of Care to Non-Physician Prescribers: The Prescription for Protecting Patients*, 35 IDAHO L. REV. 37, 58 n.82 (1998).

62. See *infra* Part III.B.5.b. (discussing the safety of ECPs).

63. See Final PATH Report, *supra* note 50, at 7.

dow, thereby increasing the likelihood of pregnancy prevention.⁶⁴ Pharmacists provide more convenient access than a woman's personal physician because a woman can see a pharmacist on evenings and weekends on a walk-in basis, while physicians often can only be reached during much more limited hours and usually require an appointment. Additionally, pharmacies tend to be conveniently located and are more easily accessible than a woman's doctor, especially if the woman is traveling far from home. Furthermore, a woman using the 1-888-NOT-2-LATE hotline⁶⁵ will find the hotline more effective if there is dependent pharmacist prescribing because an increase in available prescribers will also increase the likelihood of finding a nearby prescriber. Finally, since women in at least one study cited lack of availability of ECPs as a common reason for not using them, the increased ease of ECP access via dependent pharmacist prescribers may make women who could benefit from ECPs more likely to use them.⁶⁶

2. Dependent Pharmacist Prescribing of ECPs Lowers the Costs of Care

The use of ECPs (provided by a physician either after unprotected intercourse or in advance) is cost effective when considering "the cost of treatment, the probability of preventing an unintended pregnancy, and the cost of an unintended pregnancy[.]"⁶⁷ despite the fact that ECPs are clearly not as cost effective as pre-coital methods of contraception. For ECP prescription and dispensing, which do not really require the services of a physician,⁶⁸ allowing pharmacists to prescribe treat-

64. *See id.*

65. *See supra* Part II.D.2 (discussing the hotline).

66. *See* Laura Young et al., *Emergency Contraception: Why Women Don't Use It*, 108 N.Z. MED. J. 145, 147-48 (1995).

67. James Trussell et al., *Preventing Unintended Pregnancy: The Cost Effectiveness of Three Methods of Emergency Contraception*, 87 AM. J. PUB. HEALTH 932, 933 (1997) (evaluating the cost savings associated with the emergency contraceptive pills, taking into account the following factors: 1) whether the ECPs were provided in advance or provided when the need arose, 2) managed care and public payer settings, 3) delayed or averted birth models, and 4) the type of other methods of contraception used, and concluding that "emergency contraception is cost-effective whether provided when the emergency arises or in advance to be used as needed [and that g]reater use of emergency contraception could reduce the considerable medical and social costs of unintended pregnancies").

68. *See infra* Part III.B.5.a (discussing why the diagnosing of the need for ECPs need not be restricted to physicians).

ment can further lower the overall costs of care⁶⁹ and increase the efficiency with which we use "health care manpower."⁷⁰

Enabling a woman to obtain ECPs directly from her pharmacist reduces the woman's time and monetary costs as compared to the costs she would encounter if required to have a full doctor's visit. A single visit to the pharmacy requires less time than both a doctor's visit and a pharmacy visit. Additionally, since a woman can go to the pharmacy in the evenings or on the weekends, she is less likely to have to miss work to obtain the ECPs and incur additional salary or sick-time costs. Furthermore, easy access to ECPs can help reduce the "human" psychological and other nonmedical costs, such as loss of productivity, associated with unintended pregnancies.

Although making ECPs available through dependent pharmacist prescription may increase the costs to the pharmacist, the increase may not be as significant as some anticipate; additionally, because of the overall cost savings of the dependent pharmacist prescriber model for ECPs, pharmacists should be able to be sufficiently compensated or otherwise reimbursed for the cost increase. Pharmacists are concerned that prescribing authority may result in increased costs to the pharmacists because of "increased exposure to liability, higher insurance costs, greater paperwork burden, more time spent per patient, and the lack of

69. See Doering, *supra* note 60, at 984 (citing lower costs of care for minor conditions as a reason behind the passage of the Florida independent prescribing authority for pharmacists).

70. Maureen E. Flanagan, *Update on State Prescribing Authority*, AM. PHARMACY, Oct. 1995, at 12, 18 (discussing the American Pharmaceutical Association's goal to facilitate pharmacists' assumption of larger roles in drug therapy). As an example of the savings derived from using health care professionals more efficiently, it is instructive to look at California's experience with its "health-care manpower pilot project" that led to substantial cost savings, ultimately leading to the permanent enactment of broader pharmacist drug therapy authority. See *infra* Part IV.B.3.b.1. (discussing the current degree of authority of California pharmacists). Additionally, a review of numerous economic analyses of the effect on cost of the expansion to clinical pharmacy services has shown the benefits to dramatically outweigh the costs. See American College of Clinical Pharmacy, *ACCP Position Statement: Collaborative Drug Therapy Management by Pharmacists*, COLLABORATIVE DRUG THERAPY MANAGEMENT STATE ADVOCACY PACKET 320, 322-23 (1997) (Cara Woodson Welch, American Society of Health-System Pharmacists, ed., 1999) [hereinafter AACP Position Statement]; see also Alliance for Pharmaceutical Care, *Handouts Released at July, 1998 National Conferences of State Legislatures Annual Meeting*, COLLABORATIVE DRUG THERAPY MANAGEMENT STATE ADVOCACY PACKET 293, 294-96 (Cara Woodson Welch, American Society of Health-System Pharmacists, ed., 1999) (providing data about potential cost savings of greater incorporation of pharmacists into the health care team).

reimbursement for prescribing.”⁷¹ The liability and insurance costs should not be so significant because of the relative safety of ECPs.⁷² Although pharmacists may need to collect and retain copies of the patient history and consent/liability waivers, paperwork costs may be diminished by the ability to computerize files.⁷³ Additionally, although the pharmacists would incur more paperwork and more time spent per patient when prescribing ECPs, the Final PATH Report suggests that the pharmacists could be compensated for this additional expense by charging each woman a \$10 service fee,⁷⁴ which is certainly less than the charge that women would incur if required to have a doctor’s visit.⁷⁵ Dependent pharmacist prescription power for ECPs results in net benefits in the forms of cost savings to women and numerous other benefits to women individually and to society as a whole. These benefits significantly outweigh the additional costs and burdens placed on pharmacists and there should be a way to effectively compensate the pharmacists in order to make the prescribing authority feasible for pharmacists.⁷⁶

71. Desikan et al., *supra* note 59, at 20.

72. See *infra* Part III.B.6.a. (discussing the likely liability effects of dependent pharmacist prescribing power for ECPs).

73. See Final PATH Report, *supra* note 50, at 15.

74. See *id.*

75. However, in contrast to doctor visits, pharmacist prescribing service fees may not be covered by insurance companies. See *id.* Additionally, it is unclear whether or not the ECP itself would be covered by insurance, although coverage of contraception, in general, is increasing. See THE HENRY J. KAISER FAMILY FOUNDATION, ISSUE BRIEF — AN UPDATE ON WOMEN’S HEALTH POLICY: STATE POLICIES ON ACCESS TO GYNECOLOGICAL CARE AND CONTRACEPTION (1997) [hereinafter KFF Issue Brief]. A number of states have recently passed laws requiring private insurers covering prescriptions to cover contraception comprehensively. See *id.* at 2-3, 8. Comprehensive coverage may require inclusion of ECPs as well. Additionally, Medicaid programs have been expanding to provide increased access to family planning services to cover the entire range of birth control options, which includes OCs and IUDs, so would presumably cover ECPs as well. See *id.* at 4-5, 8. This trend of increased coverage of contraception is likely to continue to grow to reflect the public opinion that supports paying “greater attention to the health needs of women, particularly in their reproductive years.” *Id.* at 5. Thus, insurance may already cover or may expand to cover ECPs and the cost of the consultation services that accompany them.

76. See e.g., Mark Moran, *Dispensing Medical Care?*, in COLLABORATIVE DRUG THERAPY MANAGEMENT STATE ADVOCACY PACKET 318, 319 (Cara Woodson Welch, American Society of Health-System Pharmacists, ed., 1999) (discussing that a particular retail pharmacist, who gets paid for the expanded drug therapy services that he provides to his patients, “sometimes succeed[s] in receiving third-party reimbursement”). Part of this cost savings might also need to be used to compensate collaborating physicians for their time and supervisory services; this cost of compensating the physician, as remitted to the physician by the pharmacist, could be built

3. Pharmacist Prescribers of ECPs Increase Patient Satisfaction

Patient satisfaction is an important factor that should be taken into account since safety of treatment and quality of care are not significantly impacted by dependent pharmacist prescribing by dependent pharmacist prescribing of ECPs.⁷⁷ Studies have shown that interaction with pharmacists may increase satisfaction when compared to interaction with a doctor.⁷⁸ The cause of this increased satisfaction may be the combination of increased access, decreased costs, and comparable care; it may merely be a result of a better rapport between the patient and pharmacist because of a greater amount of interaction time as compared to the patient and doctor's interaction.⁷⁹ Additionally, pharmacists may be more focused on patient education than physicians,⁸⁰ leading to a higher level of patient comfort with the treatment.

In the ECP-specific context, a woman in need of ECPs may be more comfortable requesting them from someone with whom she does not have an ongoing long-term relationship because she may be embarrassed over failure to use other contraception appropriately.⁸¹ Some may counter that instead of providing women with an easy "out," we should try to foster more comfortable doctor-patient interactions; women should not be made to feel embarrassed in front of their regular physician no matter what the problem. While a completely trusting doctor-patient relationship may be ideal, the practicalities of a world of managed care hinder the development of such confidences. Additionally, even if a woman is comfortable discussing the subject matter of failed contraception with her doctor, she may be more

into the service fee charged by the pharmacist to the patient or to the patient's insurance company for the services ancillary to the ECP prescription. See *infra* note 134 (discussing, in part, compensating physicians for their collaborative services).

77. See, e.g., Coleman & Shellow, *supra* note 61, at 54-55 (arguing that patient satisfaction does not accurately reflect quality of care).

78. See Flanagan, *supra* note 70, at 17.

79. See Coleman & Shellow, *supra* note 61, at 54-55 (positing that increased patient satisfaction may come from increased time with non-physician prescribers); see also Lauren S. Christopher, *Collaborative-Practice Approach Gaining Ground in Drug Therapy Management*, *Private Sector News*, in COLLABORATIVE DRUG THERAPY MANAGEMENT STATE ADVOCACY PACKET 316 (Cara Woodson Welch, American Society of Health-System Pharmacists, ed., 1999) (citing Buck Stevens of the Mississippi Board of Pharmacy as indicating that "since the physicians work under capitated models of service reimbursement, they do not always have the time that a pharmacist can offer a patient in lengthier counseling sessions").

80. See Flanagan, *supra* note 70, at 17.

81. See Final PATH Report, *supra* note 50, at 8.

reticent to try to reach her doctor when the doctor is not on call (late at night, for example, or any other time when there is a fear that the woman may interrupt her doctor's personal life); pharmacies, on the other hand, are likely to be staffed around the clock, so a woman may feel less intrusive.

Increased patient satisfaction must be viewed with patient safety in mind. The benefit of anonymity of an unfamiliar prescriber may also be a detriment with regard to the quality of care since the prescriber is unfamiliar with the woman's entire medical history, and may not be informed as to potential risk factors in the woman's medical record. In addition, the pharmacist is unlikely to be able to either follow-up on the treatment or provide further counseling regarding ongoing contraception.⁸² However, a physician may also rely on a woman's explanation of her medical history, and thus physicians also may not have full information about a patient's medical history; additionally, physicians can not control whether a woman seeks follow-up treatment. Thus, when the advantage of increased patient satisfaction is taken together with the other advantages of dependent pharmacist prescribing of ECPs herein described, dependent pharmacist prescribing of ECPs clearly results in an overall benefit.

4. Combination of Benefits of Dependent Pharmacist Prescribing of ECPs May Aid Socio-Economically Disadvantaged Women in Particular

The benefits of increased access and decreased cost as a result of pharmacist prescribing of ECPs may have a particularly important impact on disadvantaged women. The cost of a doctor's visit may particularly burden poorer and younger women.⁸³ Additionally, these women are less likely to have medical insurance to cover the costs of ECPs and the requisite doctor visit, if in fact, insurance even covers these costs at all.⁸⁴ To the extent that insurance coverage practices may change to cover ECPs, this

82. See *infra* Part III.B.5.f. (countering the concerns about lack of follow-up care in dependent pharmacist prescribing).

83. See Kelly Blanchard, *Improving Women's Access to Emergency Contraception: Innovative Information and Service Delivery Strategies*, 53 J. AM. MED. WOMEN'S ASS'N 238, 239 (1998) (explaining that the financial burden of a doctor visit might discourage women from visiting their doctors to obtain ECP prescriptions).

84. See *supra* note 75 (discussing insurance coverage of ECPs). If ECPs are covered, cost may be particularly burdensome on those women who do not have insurance but are not poor enough to be covered by Medicaid. See KFF Issue Brief, *supra* note 75.

paper's proposed model of dependent pharmacist prescribing maintains the prescription status of the ECPs so that they may be covered under insurance prescription plans.⁸⁵ Additionally, the time required to see a doctor during regular work hours may be a particularly difficult burden for poorer women who may have less flexibility with their job hours and are less likely to be able to afford to miss time at work. If these women can obtain ECPs from pharmacists without a separate doctor's visit, the monetary and time costs that are so valuable to this group of women in particular are reduced.

Additionally, dependent pharmacist prescribers of ECPs enable women without regular reproductive health care providers to obtain ECPs.⁸⁶ This allows these women to access ECPs without the time delay of obtaining a new physician and setting up an appointment. Opponents argue that non-physician prescribing power cannot be justified as a method for access to medical care for underserved populations because it effectively creates a "two-tier" system of health care,⁸⁷ providing lower quality, non-physician health care to underserved, disadvantaged populations. While ideally all women would have a physician to whom they could turn, many women simply do not, and dependent pharmacist prescribing of ECPs does not relegate disadvantaged women to second class health care, but rather it helps to fill the gap for this time sensitive medical treatment.

5. Dependent Pharmacist Prescribers of ECPs Can Provide Comparable Quality of Care, as the Traditional Concerns About and Arguments Against Pharmacist Prescribers are Significantly Weaker in the Context of Dependent Pharmacist Prescribers of ECPs

Because ECPs have few contraindications and risks, and because the need for ECPs is relatively easy to determine, women needing ECPs are likely to be able to obtain care from pharma-

85. See *supra* note 75 (discussing insurance coverage of ECPs). To the extent that insurance companies and Medicaid may increase their coverage of ECPs, it will be important to lower-income women who rely on prescription subsidies, to maintain the prescription status of ECPs rather than increasing access by transferring them to nonprescription status which could have a regressive effect.

86. See Final PATH Report, *supra* note 50, at 8.

87. See Coleman & Shellow, *supra* note 61, at 55; see also James L.J. Nuzzo, *Independent Prescribing Authority of Advanced Practice Nurses: A Threat to the Public Health?*, 53 FOOD DRUG L.J. 35, 43 (1998).

cists of a quality comparable to the care they could obtain from a physician. The ability of dependent pharmacist prescribers to provide high quality care should allay the concerns of critics of non-physician prescribing authority who cite concern over quality of care as a major argument against expanding prescribing power. Thus, when taken together with the benefits of increased access, decreased cost, and increased patient satisfaction from dependent pharmacist prescribing, high quality of care supports the adoption of a dependent pharmacist prescribing regime for ECPs.

a) *Since the Determination of the Need for an ECP Is Made Largely By the Requesting Woman, Dispensing ECPs Does Not Require a Traditional Diagnosis*

Correctly diagnosing a medical ailment is vital to appropriate and safe treatment.⁸⁸ In some situations, proponents and critics of non-physician prescribers agree that there are situations where evaluation and correct therapy are obvious. In these situations, where “even an intelligent layperson can decide what is wrong and how to treat certain illnesses,” non-physician health care providers can implement effective treatment plans.⁸⁹ Such is the case with ECPs — women can make their own “diagnosis” because women are the ones who know if they have had unprotected intercourse at a point during their menstrual cycle that would put them at serious risk of an unintended pregnancy.⁹⁰ In fact, this “self-diagnosis” characteristic of ECPs is already recognized by many doctors who rely on the woman to decide when

88. The major concern in this section is that pharmacists do not have the requisite training and experience to accurately diagnose an ailment; therefore, critics are concerned that if pharmacists cannot accurately diagnose, they cannot be trusted to safely choose a medication prescription to treat the diagnosed problem. *See, e.g.*, Galt, *supra* note 2, at 1698 (discussing concerns that pharmacists “do not have a comprehensive set of diagnostic skills”); Moran, *supra* note 76, at 319 (“Pharmacists may know a lot about drugs, but they don’t know how to examine and take care of the whole patient.”).

89. Coleman & Shellow, *supra* note 61, at 49-50.

90. *Cf.* Charlotte Ellertson et al., *Should Emergency Contraceptive Pills Be Available Without Prescription?*, 53 J. AM. MED. WOMEN’S ASS’N 226, 227 (1998); Trussell et al., *supra* note 30, at 270. However, despite this “self-diagnosis” characteristic of ECPs, it is unlikely that they will be made available OTC. *See infra* Part III.C.1. (discussing that although ECPs may very well be safe and effective without the supervision of a medical practitioner, and thus may qualify for OTC status, the FDA is unlikely to switch ECPs to OTC status because of a concern that more information about long term repeated use of ECPs may be needed and because a switch to OTC status may be politically unpopular).

the ECP treatment is appropriate,⁹¹ and prescribe ECPs ahead of time, so these woman may use them quickly if the need ever arises. A woman can self-diagnose and self-medicate even if she does not have an ECP treatment prescribed in advance; if a woman regularly takes OCs, she can easily access instructions on the Internet to find the appropriate combination of her OCs to create her own ECP.⁹² In the dependent pharmacist prescriber model, a pharmacist receiving a request for ECPs merely needs to determine whether ECPs are appropriate. This determination does not require a traditional "diagnosis" because a physical examination is not necessary, and no tests are required to sort out the possible cause of the problem.⁹³ Instead, a pharmacist need only "evaluate" whether or not the woman has any of the easily discernible contraindications or risk factors for the treatment.⁹⁴

Pharmacists can be easily educated about ECPs so as to be sufficiently knowledgeable both to perform the requisite evaluation and inquiry into the woman's condition and to provide counseling to the requesting woman about proper administration of ECPs.⁹⁵ Part of the concern about pharmacist (or any non-physician) prescribers is that lack of training and lack of diagnostic/physical assessment skills raise questions about the prescriber's competency to safely prescribe.⁹⁶ Pharmacists feel that, in certain situations, they could be provided with "educational seminars [designed to] . . . give pharmacists the confidence and skills needed to provide such services."⁹⁷ This has been successfully done in the Washington State PATH Pilot project for the dependent pharmacist prescription of ECPs, where pharmacists, preparing to prescribe ECPs pursuant to collaborative agreements with physicians, were provided with training sessions covering topics including "therapeutic and dispensing information; patient care issues, including the need for sensitive counseling, proce-

91. See *supra* Part II.D.2.

92. See, e.g., *supra* note 46 and accompanying text.

93. See Doering, *supra* note 60, at 984 (discussing these as elements of a traditional diagnosis); Matheson et al., *supra* note 21, at 38-39 (explaining that these elements are not needed when dispensing ECPs).

94. See *infra* Part III.B.5.b.

95. See Final PATH Report, *supra* note 50, at 21 (discussing pharmacist training).

96. See Nuzzo, *supra* note 87, at 44 (expressing doctors' concerns about the lack of training and education for non-physician prescribers); Flanagan, *supra* note 70, at 17 (explaining that pharmacists may also be concerned about their lack of competency and diagnostic skills for prescribing authority).

97. Desikan et al., *supra* note 59, at 23.

dures for informed consent and service delivery to minors; information on collaborative agreements; referral to reproductive health services, including family planning clinics; insurance reimbursement issues; and public relations.”⁹⁸ Guidelines could also be developed to help pharmacists walk through the evaluation procedure with a woman requesting ECPs.⁹⁹ Additionally, with this training about ECPs, pharmacists could counsel women about proper administration of the ECP regime. The ECP administration regime, two pills as soon as possible after the unprotected intercourse and two more pills twelve hours later, is not complicated to prescribe, as the treatment does not vary from woman to woman,¹⁰⁰ nor is it complicated to follow. One study showed that almost all of the women who obtained the ECPs in advance used them correctly.¹⁰¹ While the study group may not be representative of the general population, it does indicate that women can correctly self-medicate even when given instructions regarding administration far in advance.¹⁰² Thus, if pharmacists are sufficiently knowledgeable so they can impart to a woman the same basic instructions regarding ECP use as would be provided to her well in advance by a physician or over the phone by a clinician, the woman is likely to be able to use the ECPs correctly.

Additionally, it is not a significant expansion of pharmacists’ current roles to allow a pharmacist to evaluate whether a woman needs an ECP and to counsel a woman with regard to appropriate treatment use. Because of the everyday realities of pharmaceutical practice, pharmacists already consult with patients.¹⁰³ In these everyday situations, pharmacists inquire into the situation that concerns the patient and briefly into patient’s medical history, thereby enabling the pharmacist to determine whether the condition is so serious as to require a referral to a physician or whether a more readily available treatment could safely suffice. If the pharmacist recommends a nonprescription drug as treat-

98. Wells et al., *Using Pharmacies*, *supra* note 50, at 289.

99. *See, e.g.*, Matheson et al., *supra* note 21, at 40 (providing a flowchart for pharmacist decisions regarding ECPs); *see also supra* Part III.A. (outlining the basic procedure for dependent pharmacist prescribing).

100. *See* Ellertson et al., *supra* note 90, at 227.

101. *See* Glasier & Baird, *supra* note 21, at 2.

102. *See id.*

103. *See* Doering, *supra* note 60, at 984; *see also* Galt, *supra* note 2, at 1697 (noting that “[m]any patients seek pharmacists for advice and care related to both prescription and nonprescription medications”).

ment for the ailment, the pharmacist may counsel a customer on the proper use of the treatment and advise the customer to seek the advice of a physician if she encounters certain side effects or lack of relief from the aggravating condition. This evaluatory and advising role, central to a pharmacist's daily interactions with customers, requires the same kind of evaluation that is needed when determining if ECPs are appropriate for a woman. A pharmacist's evaluation of the need for ECPs can be based solely on an inquiry into a woman's condition and her brief history.¹⁰⁴ Additionally, just as pharmacists counsel other customers about appropriate use of medication, so too could pharmacists explain to a woman how to use the ECPs and advise her of side effects of which she should be aware.

In addition to the everyday counseling of patients that accompanies pharmacist-patient interactions, pharmacists already provide the vital function of counseling patients regarding drug therapy, pursuant to Congress' mandate under the Omnibus Budget Reconciliation Act of 1990 ("OBRA '90").¹⁰⁵ OBRA '90 requires pharmacists to provide counseling services to their Medicaid patients regarding issues including dosage, drug administration schedule, duration of therapy, special directions, common severe side effects, and techniques for self monitoring,¹⁰⁶ and many states have extended these pharmacist duties to cover all prescriptions, not just those reimbursable by Medicaid.¹⁰⁷ However, the depth of information and counseling provided to a patient is left up to the pharmacist's professional judgment; the pharmacist is required to provide to the patient as much informa-

104. A pharmacist can request information similar to that requested by Planned Parenthood in their "Dial EC" program. See *supra* Part II.D.2. A sample checklist of questions that a pharmacist should ask a customer requesting ECPs in order to obtain the necessary medical history includes whether the woman 1) takes any of a list of antibiotics or drugs for epilepsy, 2) has a migraine or has a history of migraines also causing loss of feeling or partial blindness, 3) has ever had a blood clot in her veins, heart, or lungs (including stroke or heart attack), and 4) smokes. See Matheson et al., *supra* note 21, at 40.

105. Pub. L. No. 101-508, 104 Stat. 1388 (1990).

106. 42 U.S.C. §1396r-8(g)(2)(A)(ii)(I) (1994); see RICHARD R. ABOOD & DAVID B. BRUSHWOOD, *PHARMACY PRACTICE AND THE LAW* 180-83 (2d ed. 1997); see also Steven W. Huang, *The Omnibus Reconciliation Act of 1990: Redefining Pharmacists' Legal Responsibilities*, 24 AM. J.L. & MED. 417, 433-42 (1998) (discussing the impact of OBRA '90 on the duties of pharmacists).

107. See Huang, *supra* note 106, at 434; see also NATIONAL ASSOCIATION OF BOARDS OF PHARMACY, 1999-2000 SURVEY OF PHARMACY LAW 62-63 (1999) (describing state-by-state patient counseling requirements) [hereinafter NABP 2000 Survey].

tion as is appropriate given the medical circumstance.¹⁰⁸ If pharmacists were allowed to prescribe ECPs, the resulting counseling responsibilities would not be a significant expansion of the counseling services already provided by pharmacists in everyday pharmacist patient interactions and provided pursuant to OBRA '90 and state law.

The counseling responsibility that arises with dependent pharmacist prescription power for ECPs may implicate concerns about patient/prescriber confidentiality in the pharmacy.¹⁰⁹ Many women may not want to discuss intimate issues of contraception at the pharmacy counter without a more confidential environment. However, some pharmacies already have an office that would provide additional privacy for the woman to discuss her need for ECPs with the pharmacist, but others might need to build or designate such a space.¹¹⁰ Alternatively, pharmacists could ask the woman to return to the pharmacy at a specified time later in the day when the pharmacist expects there to be fewer people around; this strategy might defeat the convenience and speed purposes of allowing pharmacists to prescribe ECPs.¹¹¹ Most pharmacies should be able to provide a woman with some level of privacy, whether it be in a separate office or at the other end of the pharmacy counter, but it should be noted that while confidentiality is an important aspect to treating patients, there may need to be some trade off between privacy and convenient access. Alternatively, telephone consultation with the pharmacist about the appropriateness of the ECP therapy, followed by a mere pick-up at the pharmacy, may be an effective way to provide women with the necessary information in a confidential manner;¹¹² however, a woman desiring the strictest privacy may still choose to see a doctor about her need for ECPs rather than see a pharmacist.¹¹³ Since pharmacists have the evaluatory/diagnostic and counseling abilities to safely prescribe ECPs, the availability of the dependent pharmacist prescriber

108. See ABOOD & BRUSHWOOD, *supra* note 106, at 182.

109. See Final PATH Report, *supra* note 50, at 14.

110. *See id.*

111. *See id.*

112. *See id.*

113. Under the dependent pharmacist prescriber model, a woman has a choice. The purpose of this proposal is to provide women with options that they can choose to take advantage of if they wish. This is one of the benefits of having dependent pharmacist prescribing coexist with doctor prescribing rather than requiring these options to be mutually exclusive, which they might be if the proposal was to make ECPs available over-the-counter.

option is likely to provide a significant number of women with the tools they need to control their reproductive future in a safe and relatively private manner.

b) *The Safety Concerns and Risks Associated with ECPs Are Very Small*

ECPs have few contraindications, and even the FDA recognizes that studies have shown no serious adverse effects associated with ECPs.¹¹⁴ Thus, traditional concerns regarding severe adverse drug events and about general safety of the patients provide much weaker arguments in the context of dependent pharmacist prescribers of ECPs.¹¹⁵

While there are side effects associated with ECPs, the risks associated with these effects are not serious, and if women are aware of the possibility of experiencing these side effects, such experiences should not cause alarm. The most common side effects are nausea and vomiting, however these side effects are less likely in the levonorgestrel (progestin) only regime (23.1% of women experiencing nausea, 5.6% vomiting) than in the traditional Yuzpe regime (50% nausea, 20% vomiting).¹¹⁶ These side effects can be further reduced by taking an anti-nausea medication along with either regime. Other common side effects include fatigue, headaches, dizziness, breast tenderness, abdominal cramps, and menstrual irregularities.¹¹⁷ Although a number of women taking ECPs will not experience these side effects, dependent pharmacist prescribers can alert women to the possibility of experiencing them and mitigate the effects by recommending an anti-nausea medication. In addition, the dependent pharmacist can advise women to consult a physician (or at least reconsult the pharmacist, so the pharmacist can contact the collaborating physician) if they experience severe vomiting. Physician prescribers can do little more to reduce the possibility of experiencing side effects, and since the pharmacist collaborates with a physician, women obtaining ECPs from their phar-

114. See Glasier & Baird, *supra* note 21, at 1; FDA Notice on ECPs, 62 Fed. Reg. at 8611.

115. See, e.g., Coleman & Shellow, *supra* note 61, at 39-45.

116. See WHO Task Force on ECPs, *supra* note 12; P.C. Ho & M.S. Kwan, *A Prospective Randomized Comparison of Levonorgestrel with the Yuzpe Regimen in Postcoital Contraception*, 8 HUMAN REPROD. 389 (1993).

117. See Ho & Kwan, *supra* note 116.

macist can have access to a physician for medical care in the rare case where the side effects may become more severe.

Additionally, even the FDA acknowledges that studies have not shown teratogenic or other adverse effects on a fetus if ECPs are taken early on during an already established pregnancy; the ECP regimen is merely ineffective after implantation.¹¹⁸ Furthermore, ECPs are not addictive and an accidental overdose does not pose a serious risk.¹¹⁹

There is no significant indication in studies that ECPs pose any serious health risks. The World Health Organization does not consider there to be any contraindications to ECPs other than pregnancy.¹²⁰ Women who have contraindications for ongoing OCs may be able to safely use ECPs because the short duration of hormone use associated with ECPs makes even the minimal health risks associated with OCs unlikely.¹²¹ Even so, ECP manufacturers choose to err on the side of caution, listing the major contraindications for OCs as possible contraindications for ECPs as well.¹²² Contraindications for OCs, and thereby possibly for ECPs include: history of focal migraines, an active migraine, liver disease, stroke, heart attacks, severe hypertension, thromboembolic disease, blood clots, and hypersensitivity to any component of the product.¹²³ Additionally, cigarette smoking increases the risk of side effects with OCs, so pharmacists may want to refer women smokers to physicians.¹²⁴ Pharmacists can easily screen out,¹²⁵ and refer to physicians, women with any of

118. FDA Notice on ECPs, 62 Fed. Reg. at 8611; Glasier, *supra* note 8, at 1059-60.

119. See Ellertson et al., *supra* note 90, at 227.

120. See *id.* WHO considers pregnancy to be a contraindication for ECPs not because of any ill effects to the woman or fetus if the woman takes ECPs while pregnant, but merely because ECPs are ineffective if the woman is already pregnant. See *id.*; see also WHO Task Force on ECPs, *supra* note 12.

121. See Ellertson et al., *supra* note 90, at 228; Feminist Women's Health Center, *Emergency Contraception* (visited Oct. 26, 1999) <www.fwhc.org/ecinfo_n.htm>; Planned Parenthood ECP Fact Sheet, *supra* note 46 ("Almost every woman who needs emergency contraception can safely use ECPs — even women with contraindications to the ongoing use of oral contraceptives may use them.").

122. See GYNETICS INC., PREVEN EMERGENCY CONTRACEPTIVE KIT CONSISTING OF EMERGENCY CONTRACEPTIVE PILLS AND PREGNANCY TEST (1998) package insert available (visited Oct. 23, 2000) <<http://www.fda.gov/cder/foi/label/1998/20946lbl.pdf>> [hereinafter Gynetics, PREVEN Package Insert].

123. See JAMES OWEN DRIFE, *THE BENEFITS AND RISKS OF ORAL CONTRACEPTIVES TODAY* (1996); Matheson et al., *supra* note 21, at 40-42.

124. See DRIFE, *supra* note 123.

125. See, e.g., Matheson et al., *supra* note 21, at 40 (providing a pharmacist checklist for prescribing ECPs).

these risk factors rather than prescribing the ECPs for them directly. In this way, access to ECPs can be greatly increased for most women, while still protecting the few women who might be at a slightly greater risk from ECPs.¹²⁶

c) *Women Can Still Be Effectively Screened for Risk Factors and Contraindications Despite Pharmacists' Lack of Access to Women's Medical Records*

While a comprehensive understanding of a patient's full medical history is always desirable,¹²⁷ in the case of ECPs, it is only necessary to obtain some basic information in order to protect patients and in order to know which patients need to be referred to a physician. Furthermore, because ECPs can be prescribed in a walk-in clinic or over the phone from Planned Parenthood's "Dial-EC" program,¹²⁸ women already are able to obtain ECPs by providing only very basic information about their medical history. Screening for risk factors by a pharmacist should be at least as effective as the screening in any one of those currently available methods for obtaining ECPs without an actual doctor visit. Although there is always a risk that a woman may leave out important information if the prescriber does not have access to the woman's full medical records, by asking specific questions about age, smoking habits, migraine history, antibiotic use, epilepsy, and history of heart attacks/stroke,¹²⁹ pharmacists and clinical practitioners will be able to obtain the needed information from women. Additionally, the contraindications and risks are so small that almost any woman can take ECPs regardless of her medical background.¹³⁰ Furthermore, any health care professional should be able to rely on the truth-

126. See Hatcher et al., *Public Policy Changes Needed* (visited Oct. 26, 1999) <<http://thriveonline.com/sex/contech/contraceptive.emer9.html>> ("Current prescription requirements [for ECPs] are intended to protect the small minority of women who might suffer harmful health effects that could be prevented by professional supervision.").

127. See Coleman & Shellow, *supra* note 61, at 50 ("[T]he absence of a comprehensive medical background increases the probability that atypical cases will be misdiagnosed.").

128. See *supra* Part II.D.2.

129. See *supra* Part III.A. (discussing the process through which a dependent pharmacist prescriber determines whether an ECP prescription would be safe and appropriate).

130. See *supra* Part III.B.5.b. (listing the risk factors about which pharmacists should inquire); see also Matheson et al., *supra* note 21, at 40 (providing a checklist of questions for a pharmacist to ask before prescribing and dispensing ECPs).

fulness of a woman's answers to medical questions, since it is unlikely that a woman would want to jeopardize her own health.

d) *Patient Safety Is Also Protected Through the Collaborative Agreements That Preserve the Requisite Level of Checks and Balances Between Doctors and Pharmacists.*

Dependent pharmacist prescribing of ECPs protects patient safety through collaboration, despite the lack of separation between prescriptive and dispensing powers. Generally, separation of diagnostic/prescriptive powers and dispensing powers, as a system of checks and balances, is regarded as important in order to ensure that patients get correct medications and in order to help protect against drug interaction problems.¹³¹ However, the traditional concern of the prescriber prescribing the wrong medication for the patient's condition is not particularly relevant in the ECP situation where there are only two available on-label formulations of ECPs and either would suffice for women concerned about an unintended pregnancy. As the separation of dispensing and prescribing functions becomes somewhat less relevant in an integrated and evolving health care system,¹³² that separation is of less importance in the context of ECPs in particular. Since ECPs are generally safe,¹³³ there is little risk of dangerous drug interactions, and risk can likely be screened for in the pharmacist patient consultation.

The collaborative nature of the agreement between pharmacists and physicians provides sufficient checks and balances to protect patient safety for the prescription of ECPs. As evidenced by the Washington State PATH Pilot Project, physicians and pharmacists can meet on a schedule established by the collabora-

131. See, e.g., Flanagan, *supra* note 70, at 17; C. Edwin Webb, *Prescribing Medications: Changing the Paradigm for a Changing Health Care System*, 52 AM. J. HEALTH-SYS. PHARMACY 1693, 1693 (1995) (noting that the purpose of separating the prescribing and dispensing functions is to "maintain a system of checks and balances that helps ensure a high quality of care" and also includes "avoiding real or apparent conflict of interest on the part of a practitioner who stood to profit from both recommending and selling a prescribed medication; providing a review process to help prevent medication errors, interactions, dosage errors, and related problems; and establishing duplicate (but often incomplete) systems of documentation").

132. See Webb, *supra* note 131, at 1693 (noting the transition from a separated system of prescribing and dispensing to a more integrated system in light of the "[f]undamental changes [that] are occurring in health care delivery, financing, and systems of technology and information support").

133. See *supra* Part III.B.5.b.

tive protocol so that the physician can "perform a quality assurance review of the prescribing decisions according to mutually [as between the physician and pharmacist] acceptable criteria."¹³⁴ Also, pharmacists can refer difficult or questionable cases to physicians. Some women who present difficult cases may not have a primary physician to whom they could turn, but because of the collaborative nature of the relationship between the pharmacist and the physician, pharmacists could refer those women to the collaborating physician. Alternatively, the pharmacist could refer women to clinics like Planned Parenthood that have physicians available. Under this system, dependent pharmacists prescribing of ECPs could help eligible women in the pharmacy and could act as a much needed entry point into the health care

134. PATH, ECP Collaborative Agreement, *supra* note 52.

The collaborating physicians in the PATH pilot project met regularly with the collaborating pharmacists to perform a quality assurance review. See Final PATH Report, *supra* note 50, at 13. Furthermore, since protocols under the Washington state system must be reapproved by the state Board every two years, compliance with the state regulatory supervisory requirements may be reviewed. WASH. ADMIN. CODE §246-863-100 (West, WESTLAW through Jan. 5, 2000); see also *infra* Part IV.B.1.a. (discussing the requirements of Washington model dependent pharmacist prescribing). Documentation of regular quality assurance and consultation between the pharmacist and physician may be a factor when the Board evaluates the protocol for effectiveness before reapproving it. "The primary responsibility for authorizing protocols and supervising pharmacist conduct under the protocol would rest with the authorizing practitioner who is party to the protocol agreement. The Board's role is to ensure that prescribing protocols are properly prepared and filed and that pharmacists are practicing under these guidelines." Fuller et al., *supra* note 59, at 740-41 (discussing the allocation of the supervision responsibilities). Furthermore, in a study of the participation of pharmacists and physicians in ongoing collaborative prescribing relationships, pharmacists felt that "prescriber participation is satisfactory" (86%) and that "feedback on decisions made is satisfactory" (64%). *Id.* at 744. As to their "overall satisfaction with [the] protocol program," "98% of prescribers and 95% of the pharmacists were either very satisfied or satisfied." *Id.* at 743-44.

Furthermore, the collaborating physicians can be compensated for this supervisory/collaborative service, because, as discussed in the context of compensating the pharmacists, see *supra* Part III.B.2., the increase in the net benefits from dependent pharmacist prescribing exceed the costs therefrom, so part of that cost savings can be used to compensate the involved health care practitioners. Pharmacists could either pay the collaborating doctor an annual consultation fee or a fee based on the number of cases reviewed. The PATH survey of physicians, who prescribed ECPs in the course of their practice, indicated that "[r]egarding the level of compensation that would be required for sponsoring a pharmacist and overseeing the collaborative agreement, 38 percent of respondents felt an annual consultation fee and 35 percent felt a fee based on chart review would be necessary." Final PATH Report, *supra* note 50, at attach. 4-2. The cost of compensating the collaborating doctor would likely be small and could be built into the service fee charged by the pharmacists for the prescribing services. See *supra* Part III.B.2. (discussing the possible compensation of the pharmacist from the overall cost savings from dependent pharmacist prescribers).

system for women in need of a reproductive health care provider, women who might not know where else to turn.

e) *Misuse of ECPs Is Unlikely.*

Women with easy access to ECPs are unlikely to rely on ECPs as their primary method of contraception. One study found that “[t]he women [who had ECPs available to them at home dispensed in advance of need] . . . were not more likely to use emergency contraception repeatedly. Their use of other methods of contraception was no different from that of the women in the control group [who had to see a physician for an ECP prescription if needed].”¹³⁵ This result is in contrast with concerns that increased access leads to an increase in misuse,¹³⁶ which in the context of ECPs would be if women used ECPs too frequently, relying on them rather than relying on more reliable methods of contraception, or if increased access encouraged promiscuity and risk taking.¹³⁷

While some women may assume more risk and less contraceptive responsibility because of easier availability of ECPs, this result is not likely to be significant for three reasons. First, ECPs are less effective than almost any pre-coital method of contraception.¹³⁸ Second, while not all women experiences side effects and while side effects can be mitigated by anti-nausea medications, many women will experience some side effects, the most common being nausea and vomiting,¹³⁹ and these side effects are likely to discourage frequent use.¹⁴⁰ Third, the high cost of ECPs

135. Glasier & Baird, *supra* note 21, at 1.

136. See *Value of Third Drug Class Not Proven*, 55 AM. J. HEALTH-SYS. PHARMACY 524 (1998) (expressing concerns about potential drug misuse); see also GENERAL ACCOUNTING OFFICE, NONPRESCRIPTION DRUGS: VALUE OF A PHARMACIST-CONTROLLED CLASS HAS YET TO BE DEMONSTRATED (Aug. 24, 1995) [hereinafter GAO Report].

137. See Glasier & Baird, *supra* note 21, at 1 (providing background to a study that demonstrated that women with easy access to ECPs in fact behaved responsibly).

138. See Ellertson et al., *supra* note 90, at 228; Tamar Nordenberg, *Protecting Against Unintended Pregnancy: A Guide to Contraceptive Choices*, FDA CONSUMER, Apr. 1997, at 20 (providing the efficacy rates for the prevention of unintended pregnancies for the following methods of contraception: oral contraceptive pills (combined estrogen/progestin or progestin-only) — over 99%; depo-provera — over 99%; male or female sterilization — over 99%; norplant — 98-99%; IUD - 98-99%; male condom — 88%; diaphragm with spermicide — 82%; periodic abstinence — 80% (but highly variable); female condom — 79%; ECPs — 75%).

139. See *supra* Part III.B.5.b.

140. See Trussell et al., *supra* note 30, at 270.

when compared to the cost of ongoing pre-coital contraception may be a barrier to overly frequent use.¹⁴¹ These factors discourage repeated use of ECPs; thus, women are unlikely to behave in a riskier, more promiscuous fashion merely because of easier availability of ECPs. Instead, increased access to ECPs fills a gap helping women who, despite their regular contraceptive habits, find themselves concerned about an unintended pregnancy.

While some pharmacists involved in the Washington State PATH Pilot Project suggested that a system should be installed to identify chronic users of ECPs, so that pharmacists could refer such women to physicians rather than prescribing ECPs directly for them, this might entail substantial extra cost, depending on the information technology already available.¹⁴² A better solution may be to rely on "educational messages around the issue of taking personal responsibility . . . [in order to] reduc[e] the degree of ECP abuse[.]"¹⁴³ and on women themselves.

f) *Although Pharmacist Prescribing of ECPs Does Not Provide the Same Opportunities as Physician Prescribing for Patient Follow-Up, The Relevant Follow-Up Does Not Relate to Safety Concerns Caused by the Use of ECPs, and as Such, Dependent Pharmacist Prescribing Power for ECPs Should Not Be Denied on This Basis*

While the administration of some medications requires monitoring of patients for adverse side effects,¹⁴⁴ this concern is less pronounced in the context of ECPs because of the limited seriousness of potential side effects.¹⁴⁵ There is not a lot of need to monitor long and short term effects because "[t]he well-established characteristics of the regimen make it unlikely that unanticipated long-term negative side effects would be observed. Duration of the therapy . . . and half-life of the drugs are both short. The short-term side effects are well known and can easily be managed by the woman herself."¹⁴⁶ In the course of the initial consultation, a pharmacist should inform the woman about potential side effects so that she is not alarmed if she experiences

141. See Final PATH Report, *supra* note 50, at 16. The "real" cost difference would be even more significant if other methods of contraception were covered by insurance while ECPs were not. See *supra* note 75.

142. See Final PATH Report, *supra* note 50, at 15-16.

143. See *id.* at 16.

144. See Coleman & Shellow, *supra* note 61, at 50-51.

145. See *supra* Part III.B.5.b.

146. Ellertson et al., *supra* note 90, at 227-228.

them; additionally, a pharmacist can inform the woman that she should return to the pharmacy or consult her own doctor if anything out of the ordinary occurs. If serious side effects arise, a woman maintains easy access to her pharmacy and can consult with the pharmacist; the pharmacist can counsel the patient as to the normality of the side effects or can refer the patient to the collaborating or other physician.

However, after a pharmacist or physician prescribed ECP treatment there is a concern about follow-up regarding ongoing contraception and risks of sexually transmitted diseases (“STDs”).¹⁴⁷ ECPs do not protect against STDs,¹⁴⁸ and women should be informed that they should get tested for STDs if there is even a small chance of risk. Additionally, use of ongoing contraception is more effective at preventing unwanted pregnancies than use of ECPs¹⁴⁹ and is thus clearly preferable; women should be encouraged to pursue options for ongoing contraception rather than relying on ECPs. In addition to the package insert that already comes with the ECP package,¹⁵⁰ another suggestion for mitigating the follow-up concern is for pharmacists to distribute a condom with every ECP prescription, along with the relevant referral information.¹⁵¹ Other suggestions for educating patients include “patient information booklets, pamphlets . . . wallet cards, and point of sale displays.”¹⁵² Furthermore, women should have regular gynecological check-ups and pap smears to ensure reproductive health. Pharmacists should inform women requesting ECPs about these issues, and they should recommend that the women see their doctor for a medical follow-up after three weeks, especially if they have not had their next period by that time.¹⁵³ However, conditioning ECP prescriptions on gynecological exams, pap smears, and physician counseling regarding ongoing contraception seems merely paternalistic.

The recommended follow-up for ECPs is largely prospective, looking ahead to preventing future unwanted pregnancies through ongoing contraception, and only retrospective in the sense that there may be a concern for an actual pregnancy or

147. See Final PATH Report, *supra* note 50, at 8.

148. See Gynetics, PREVEN Package Insert, *supra* note 122.

149. See Trussell et al., *supra* note 5; see also *supra* note 138.

150. See, e.g., Gynetics, PREVEN Package Insert, *supra* note 122.

151. See Final PATH Report, *supra* note 50, at 15.

152. *Id.* at attach. 3-2 (surveying pharmacists regarding possible methods for helping patients understand issues surrounding ECPs).

153. See Matheson et al., *supra* note 21, at 42.

STD. The follow-up is not needed in order to address a health or safety risk posed by the ECP itself. Thus, the inability to procure this follow-up treatment for women requesting ECPs should not be a barrier to ECP prescription from pharmacists. Many women who receive ECPs from their doctors do not have follow-up care.¹⁵⁴ If pharmacists were required to ensure that women received follow-up care after the dispensation/prescription of ECPs, that might defeat the easy access and reduction of unintended pregnancies purposes of having ECPs available through pharmacies. Additionally, while prescription of ECPs without follow-up regarding ongoing contraception and reproductive health may not be ideal, such prescription is more helpful than hurtful. It is better for a woman to contract an STD but be able to minimize her risk of an unwanted pregnancy rather than for the same woman to face the problems of both an STD and an unwanted pregnancy. If ECPs are available only through a doctor's prescription, women incur higher transaction costs when trying to obtain ECPs as compared to the costs of obtaining the ECPs directly from pharmacists; thus, instead of incurring the higher costs to see a doctor for an ECP prescription, more women may take a "wait-and-see" approach, only visiting a doctor if they believe they are in fact pregnant.¹⁵⁵ Requiring women to see a physician in order to obtain ECPs would not significantly increase the number of women who obtain reproductive health care, it would merely reduce the number of women who could have another chance to control their reproductive futures and it would fail to allow ECPs to have their full potential effect on the reduction of unwanted pregnancies.¹⁵⁶ Dependent pharmacist prescribing power for ECPs can make a bad situation better, allowing women to reduce the likelihood of unintended pregnancies while getting a minimal level of counseling regarding ongoing contraception and getting encouragement to see a physician.

154. *See id.*

155. *See* Center for Reproductive Law & Policy, *The Facts: Emergency Contraception* (visited Oct. 19, 1999) <<http://www.crlp.org/ecdomestic.html>> [hereinafter CRLP, *Emergency Contraception*] (reporting that 42% of women who obtained ECPs directly from a pharmacist in the Washington State Pilot Project would have taken no action and would have just waited to find out if they were pregnant if they had not obtained ECPs from pharmacists).

156. *See generally* Trussell et al., *supra* note 30 (arguing that increased access to ECPs can reduce the number of unintended pregnancies).

g) *Limited Dependent Pharmacist Prescribing Power Is Unlikely to Lead to Expansive Prescribing Power that Could Implicate the Above-Mentioned Concerns*

There are numerous limitations on the scope of dependent prescribing of ECPs¹⁵⁷ thus preventing the possible “open[ing] the floodgates” for pharmacists to be able to prescribe all sorts of medications, many of which may cause significant patient care concerns. This prescriptive power is carefully circumscribed by both the state laws and regulations.¹⁵⁸ Additionally, the state boards of pharmacy, although interested in enabling their member pharmacists to acquire a strong role in the health care process, are concerned about liability and patient safety as well.¹⁵⁹ In most states where there are some types of collaborative practice, a board composed of members from the state Boards of Pharmacy and Medicine carefully review protocols for approval.¹⁶⁰ Additional checks on expanding dependent pharmacist prescription power are provided by physicians who are concerned themselves with safety and liability and without whom no collaborative agreements could be created, by insurance companies that may circumscribe the activities of their insurees to ensure minimal liability exposure, and by the drug manufacturers themselves who can discontinue distribution of their drugs if they are concerned about liability as a result of the prescription/distribution method. The effectiveness of these checks on the prevention of expansion of pharmacist prescription privileges is evidenced by the small number of collaborative drug therapy agreements on file in states, like Washington, whose laws have allowed them for years.¹⁶¹ Since this move toward dependent

157. “Opponents of the [Florida] law [allowing pharmacists to prescribe medications on a listed formulary] have expressed concern that the scope of the medications on the list will be broadened beyond original intentions.” Doering, *supra* note 60, at 984. However, in Florida, adding an item to their formulary of medications that pharmacists can prescribe requires an act of the legislature. *See id.*

158. *See, e.g.*, WASH. ADMIN. CODE § 246-863-100 (West, WESTLAW through Jan. 5, 2000).

159. *See Fuller et al., supra* note 59, at 741 (explaining that collaborating physicians and pharmacists have to file their collaborative drug therapy agreement with the state board of pharmacy for review).

160. *See, e.g., infra* Part IV.B. (discussing the requirements for protocols in various states).

161. *See Fuller et al., supra* note 59, at 740-42 (stating that as of 1996 only 61 protocols, involving 1,650 prescribers and 425 pharmacists, were on file in Washington, even though Washington has had collaborative agreement laws since 1981). There are now over 415 protocols on file in Washington, but a large number of those

pharmacist prescribing power for ECPs is relatively controversial,¹⁶² it is likely that moving other drugs to dependent pharmacist prescription status will be equally controversial, and thus similarly studied and discussed.

6. Hurdles to Effective Implementation of Dependent Pharmacist Prescribing of ECPs Are Surmountable

A number of obstacles stand in the way of enabling dependent pharmacist prescribing in various states and in the way of actually getting the majority of pharmacists and doctors to participate in the collaborative program for increasing access to ECPs through dependent pharmacist prescribers.¹⁶³ In addition to pharmacist/physician concerns about being paid for the services required as part of dependent pharmacist prescribing,¹⁶⁴ pharmacists and doctors are concerned about additional liability. Also, because there is still confusion among pharmacists about whether ECPs are contraception or abortifacients, some pharmacists may be disinclined to help increase access to ECPs; in fact, some may try to rely on state conscience clauses to protect them from even having to dispense ECPs. Additionally, there is some political opposition to ECPs in general, and the medical community largely opposes the idea of non-physician prescribers.

a) *While Concerns About Legal Liability May Decrease Pharmacists' Willingness to Take on the Risks and Responsibilities of Prescribing ECPs, Actual Liability Risks to Pharmacists Should Be Minimal Because of the Good Safety Profile of ECPs*

Increased liability is one of the major concerns that pharmacists and physicians harbor when considering dependent pharmacist prescribing.¹⁶⁵ However, there are a few reasons why

are protocols for ECPs. Telephone Interview with Tim Fuller, Pharmacy Consultant, Washington State Board of Pharmacy (Jan. 18, 2000).

162. See *infra* Part III.B.6.c.

163. See Galt, *supra* note 2, at 1697 (noting that even if states legally enable dependent pharmacist prescribing, "[t]his does not mean that all pharmacists should be expected or required to accept such prescribing authority"). However, in order for dependent pharmacist prescribing of ECPs to have the impact that this paper asserts that it can have, there needs to be as few factors as possible discouraging the pharmacists from assuming the authority.

164. See *supra* Part III.B.2.

165. See Desikan et al., *supra* note 59, at 20-21 (discussing concerns about liability); Flanagan, *supra* note 70, at 17 (same); Final PATH Report, *supra* note 50, at 16 (same).

dependent pharmacist prescribing does not pose a great enough liability threat to impede pharmacists from assuming the responsibility of dependent pharmacist prescribing. First, the causes of action against a dependent pharmacist prescriber do not expose the pharmacist to much greater liability than the causes of action available against pharmacists currently because pharmacists' duties have evolved recently to encompass a great deal. Second, even if liability could increase as a result of dependent pharmacist prescribing, the scope and breadth of delegation of prescriptive power by physicians is reigned in both by insurance carriers who control the market for malpractice insurance and by practitioners who are cautious about the health of their patients and their careers. Finally, and most importantly, the strong safety profile of ECPs makes it very unlikely that any suits will be initiated.¹⁶⁶

The vast majority of the liability concerns remain constant regardless of pharmacist prescribing.¹⁶⁷ Certainly a plaintiff can still sue manufacturers for product defects,¹⁶⁸ and can still sue pharmacists who negligently fill prescriptions.¹⁶⁹ To the extent

166. In fact, it seems as if the greatest potential source of liability for prescribers/dispensers of ECPs comes from *failure* to provide ECPs or information about ECPs; in addition to that liability described during the discussion of conscience clause, *infra* Part III.B.6.b, such health care professionals might even face a suit for wrongful pregnancy. See generally Gregory G. Sarno, Annotation, *Tort Liability for Wrongfully Causing One to Be Born*, 83 A.L.R.3d 15 (1978) (discussing wrongful pregnancy/birth suits).

167. This discussion is an introduction to and an overview of some liability issues surrounding prescription drugs. It is not meant to be a comprehensive analysis of all of the liability implications of pharmacist prescribing. An in depth analysis of liability implications of expanded pharmacists roles could be the subject of numerous other books and articles. See, e.g., ABOOD & BRUSHWOOD, *supra* note 106, at 229-52; DAVID B. BRUSHWOOD, *PHARMACY MALPRACTICE: LAW AND REGULATIONS* (2d ed. 1998); Linda Willett Brakins, *The Liability of Physicians, Pharmacists, and Hospitals for Adverse Drug Reactions*, 34 DEF. L.J. 273 (1995); Huang, *supra* note 106, at 433-42; Roseann B. Termini, *The Pharmacist Duty to Warn Revisited: the Changing Role of Pharmacy in Healthcare and the Resultant Impact on the Obligation of a Pharmacist to Warn*, 24 OHIO N.U. L. REV. 551 (1998). Rather, this section is intended to generally address some of the liability concerns around dependent pharmacist prescribing and intended merely to supplement the major argument in this section that, because of the good safety profile of ECPs, the additional liability risk on pharmacists as a result of the assumption of the responsibility for dependent pharmacist prescribing of ECPs is minimal.

168. See generally BRUSHWOOD, *supra* note 167, at 269-290; Jay M. Zitter, Annotation, *Liability of Manufacturer or Seller for Injury or Death Allegedly Caused by Use of Contraceptive*, 54 A.L.R.5th 1 (1999).

169. See generally BRUSHWOOD, *supra* note 167, at 155-198; Timothy E. Travers, *Druggist's Civil Liability for Injuries Sustained as a Result of Negligence in Incorrectly Filling Drug Prescriptions*, 3 A.L.R.4th 270 (1981).

that a patient may wish to sue her pharmacist for failure of the performance of the pharmacist prescribers' duty to warn her about risks in conjunction with the prescriptive activity, this liability may be only slightly greater than a non-prescriber pharmacists' duty to warn patients about drug risks, as a non-prescriber pharmacist's duty to warn is an increasingly significant requirement in many jurisdictions.¹⁷⁰ Pharmacists' duties with regard to their patients have already evolved to place more responsibility on pharmacists for their patients' drug use,¹⁷¹ thus limited dependent prescriptive power may add little to these already existing duties and resultant liabilities.¹⁷²

Even if the liability risks of pharmacist prescribing are greater than described above, as they may be in some cases, the market force of insurance carriers will limit pharmacist prescribing authority from expanding into areas that could pose more significant liability risks to either pharmacists or collaborating physicians. Malpractice insurance companies are conscious of the scope of practice of those professionals insured by the company, and adjust their premiums to the general risks of the practice and to any major specific risks of the individual. To the extent that insurance carriers are aware that their insurees are taking on risky practices, the malpractice insurance companies can respond with higher premiums. For this reason and for reasons attributable to concerns about patient safety, practitioners themselves are often hesitant to engage in risky behaviors. The absence of a significant threat from liability suits against dependent pharmacist prescribers and their collaborating physicians is evidenced by the fact that although "Washington state has had prescriptive authority for pharmacists since 1979[,] [t]o date there have been *no* legal suits brought against pharmacists operating under prescribing protocols or their collaborating physicians/cli-

170. See BRUSHWOOD, *supra* note 167, at 231-90; Tara L. Furnish, *Departing From the Traditional No Duty to Warn: A New Trend for Pharmacy Malpractice?*, 21 AM. J. TRIAL ADVOC. 199 (1997); Jill Casson Owen, *The Pharmacist's Duty to Warn: Lasley v. Shrake's Country Club Pharmacy*, 37 ARIZ. L. REV. 677 (1995). These expanded duties to warn are in part derived from the expanded counseling requirements placed on pharmacists by OBRA '90 and subsequent state expansion. See, e.g., John C. West & David E. Smith, *A Prescription for Liability: The Pharmacy Mandate of the Budget Reconciliation Act of 1990 and Its Impact Upon Pharmacists' Common Law Duties*, 2 J. PHARMACY & L. 127 (1994).

171. See BRUSHWOOD, *supra* note 167, at 291-310.

172. See generally Joseph L. Fink III, *Liability and the Changing Role of Pharmacists*, AM. PHARMACY, Dec. 1995, at 34 (rejecting the argument that pharmacist prescribers will face significantly higher costs and liability).

nicians.”¹⁷³ This fact supports the contention that pharmacists and physicians are concerned about the safety of their patients and are loathe to engage in practices that would threaten their patients and thereby threaten their careers.

In addition to the lack of major liability associated with dependent pharmacist prescribing in general, dependent pharmacist prescribing of ECPs is particularly nonproblematic because ECPs are so safe. Even Washington State’s largest physicians insurer concurs that the liability risks associated with dependent pharmacist prescribing of ECPs are minimal because of the comprehensive and sound prescribing protocols, that must be approved by the state and because ECPs “have a very good safety profile.”¹⁷⁴ Because women are extremely unlikely to be injured as a result of taking ECPs, they are unlikely to have a cause of action that could serve as a basis for a liability suit, and where there are no suits, there should be no liability concerns.

b) *While Confusion About Whether ECPs Are Contraception or Abortion May Make Some Pharmacists Reluctant to Engage in Dependent Pharmacist Prescribing of ECPs, the Overall Goal of Increased Access Should Not Be Thwarted By Conscience Clauses, Under Which Pharmacists Might Try to Refuse to Dispense ECPs at All, Because Conscience Clauses May Not Apply to ECPs, and Because Even if They Do, Pharmacists May Still Be Under an Obligation to Inform Women About How to Obtain ECPs*¹⁷⁵

Health care providers may be reluctant to help increase access to ECPs because of concerns about the nature of the ECP

173. Program for Appropriate Technology in Health, Liability Risk (received by author Feb. 1, 2000) (on file with author and with PATH).

174. *Id.* (discussing a consultation with Michael Lloyd, Risk Management Department, Physicians Insurance, regarding the liability risks posed by dependent pharmacist prescribing of ECPs); see *supra* Part III.B.5.b. (discussing the risks posed by ECPs).

175. An in depth analysis of different states’ conscience clauses and their impacts on the dispensing of ECPs is beyond the scope of this paper. See generally Kathleen M. Boozang, *Deciding the Fate of Religious Hospitals in the Emerging Health Care Market*, 31 HOUS. L. REV. 1429, 1481-93 (1995) (providing an extensive discussion of conscience clauses in the context of abortion); Bruce G. Davis, *Defining the Employment Rights of Medical Personnel Within the Parameters of Personal Conscience*, 3 DET. C.L. REV. 847 (1986); Lynn D. Wardle, *Protecting the Rights of Conscience of Health Care Providers*, 14 J. LEGAL MED. 177, 219-30 (1993); American Pharmaceutical Assoc., *1997-98 Policy Committee Report: Pharmacist Conscience Clause* (visited Jan. 9, 2000) <<http://www.aphanet.org/lead/committee2.html>> [hereinafter American Pharmaceutical, 1997-98 Policy Committee

mechanism. Under the view that pregnancy begins at the moment of fertilization, ECPs, which may work by preventing implantation, may be viewed by some as termination of a pregnancy, and thereby abortion.¹⁷⁶ However, under the FDA's and American College of Obstetricians and Gynecologists' definition of the beginning of pregnancy as implantation of the fertilized egg in the uterus, regardless of the mechanism through which ECPs function, ECPs do not affect an already existing implanted fertilized egg, so ECPs should be classified as contraception and not abortion.¹⁷⁷ The classification of ECPs as contraception rather than as abortion is supported by the court's reasoning in *Brownfield v. Daniel Freeman Marina Hospital*, where the court found that, in accordance with the relevant law, emergency contraceptive pills "constitute 'prevention,' i.e. birth control, rather than 'termination,' i.e. abortion."¹⁷⁸ Nevertheless, some pharmacists still view ECPs as abortifacients and would thus be reluctant to create a protocol for dependent pharmacist prescribing, which would promote something to which the pharmacist is opposed.¹⁷⁹

The goal of increased access through dependent pharmacist prescribing of ECPs would be thwarted if, in addition to refusing to enter into protocols for dependent pharmacist prescribing of ECPs, pharmacists could also choose not to dispense ECPs even

Report]. The discussion in this paper is intended to merely give a sense of the debate around how conscience clauses affect pharmacists faced with filling prescriptions for ECPs and to give an introduction to the scope of possible implications of pharmacist conscience clauses on this paper's goal of increasing access to ECPs.

176. See Katherine A. White, Note, *Crisis of Conscience: Reconciling Religious Health Care Providers' Beliefs and Patients' Rights*, 51 STAN. L. REV. 1703, 1715 (1999) (quoting a Catholic Ethical and Religious Directive).

177. See *id.*; see also Susan Saylor, *The Legal Status of the Morning-after Pill: Abortion or Birth Control*, 25 U.S.F. L. REV. 401 (1991) (concluding that ECPs should be classified as contraception and not abortion).

178. *Brownfield v. Daniel Freeman Marina Hosp.*, 256 Cal. Rptr. 240, 245 (Cal. Ct. App. 1989). The *Brownfield* court consequently concluded that the California law preventing religious hospitals from being liable for refusing to perform an abortion "does not immunize respondent [religious hospital] from liability for failure or refusal to provide information about estrogen pregnancy prophylaxis to rape victims." *Id.*

179. See, e.g., Kaiser Family Foundation, *Contraception & Family Planning — Conscience Clauses: Fox News Profiles Pharmacies Refusing to Dispense EC*, KAISER DAILY REPROD. HEALTH REP., Apr. 16, 1999 (visited Jan. 7, 2000) <<http://report.kff.org/archive/repro/1999/04/kr990416.4.html>>; Kaiser Family Foundation, *Contraception & Family Planning — Conscience Clauses: Some Pharmacists Continue to Wrestle with EC*, KAISER DAILY REPROD. HEALTH REP., July 29, 1999 (visited Jan. 7, 2000) <<http://report.kff.org/archive/repro/1999/07/kr990729.3.html>>.

when presented with a doctor's prescription. While some pharmacists may argue that they can choose not to dispense ECPs pursuant to their state's conscience clause, there is debate about the applicability of conscience clauses to pharmacists and to ECPs. This controversy struggles to balance both a pharmacist's right to refuse to provide medicine in accordance with the pharmacist's beliefs and a patient's right to medical care when needed.¹⁸⁰ "Conscience clauses are provisions of state and federal legislation that permit doctors, other medical personnel, and sometimes pharmacists, to refuse to perform any procedure or dispense any medication to which they have a moral or religious objection."¹⁸¹ If a state's conscience clause applies to pharmacists¹⁸² and to ECPs, pharmacists in that state could refuse to fill a prescription for ECPs if they morally or religiously objected to ECPs. However, the state conscience clauses vary greatly in coverage, and a number apply to abortion and not to contraception; so ECPs may not fall under the conscience clause protection in these states.¹⁸³

Even if conscience clauses do enable pharmacists to refuse to dispense ECPs, the goal of increasing access is not defeated because pharmacists may have a duty to "help customers access the prescriptions in question, whether that means 'leaving a prescription to a partner, giving it to another store, or handing a patient a toll-free hotline number, such as one set up by proponents of emergency contraception.'"¹⁸⁴ Similarly, the court in *Brownfield* held that a hospital had a duty to help a woman access medical care and thus could be held liable for refusing to

180. See, e.g., American Pharmaceutical, *1997-98 Policy Committee Report*, *supra* note 175 (discussing the difficulty of balancing the pharmacists' role as health care professionals, where they must provide medical care when it is needed, with the pharmacists rights as individuals, where they should be able to remove themselves from situations they find morally or religiously objectionable).

181. CRLP, *Emergency Contraception*, *supra* note 155.

182. Not all states have conscience clauses that cover pharmacists, so it is unclear to what extent the conscience clauses could be invoked to help a pharmacist who does not wish to fill a prescription for ECPs. See generally American Pharmaceutical, *1997-98 Policy Committee Report*, *supra* note 175 (discussing the issues surrounding conscience clauses for pharmacists, particularly with regard to reproductive health issues).

183. See *supra* notes 176-80 and accompanying text.

184. Kaiser Family Foundation, *Contraception & Family Planning — Emergency Contraception: 'Crisis at the Pharmacy Counter'*, KAISER DAILY REPROD. HEALTH REP., Mar. 29, 1999 (visited Jan. 7, 2000) <<http://report.kff.org/archive/repro/1999/03/kr990329.3.html>>.

provide information about emergency contraception to a rape victim.¹⁸⁵

Thus, while no pharmacist has a duty to create a collaborative agreement under which the pharmacist could exercise dependent prescriptive authority for ECPs, and pharmacists may be able to refuse to dispense ECPs pursuant to a conscience clause if the pharmacist objects on moral or religious grounds, all pharmacists may have a duty to at least provide information about how to obtain ECPs to women requesting them. This duty helps to mitigate the effect of dissenting pharmacists who might otherwise validly decline to prescribe ECPs on moral, religious, or personal grounds. Thus, while pharmacists are not obligated to exercise dependent pharmacist prescribing of ECPs, conscience clauses may not wholly excuse pharmacists from playing at least a small role in helping women obtain emergency contraception, where a state decides to change its laws in order to increase access to ECPs.

c) *The Threat of Political Opposition Both to Dependent Pharmacist Prescribers and to ECPs Is Mitigated by the State-By-State Character of This Proposal*

(1) *Political Opposition to Dependent Pharmacist Prescribers*

The majority of the political opposition towards dependent pharmacist prescribers comes from the medical community, who may fear erosion of their authority. Each side, physicians and pharmacists, argues that it is looking out for the best interests of patients, while the other side is merely trying to make a profit and self-aggrandize.¹⁸⁶ While resistance to breaking down the

185. *Brownfield*, 256 Cal. Rptr. at 243-45.

186. See Moran, *supra* note 76, at 318-19 (discussing the medical community's reaction to the prospect of pharmacist prescribing, quoting one doctor as saying, "I don't need him [a pharmacist] to do my job for me[,] and explaining that state medical societies see the push for pharmacist prescribing as "an economically driven strategy, supported by the interests of chain drug stores . . . [that was] designed by pharmacists seeking to practice medicine"); Coleman & Shellow, *supra* note 61, at 58 (discussing "turf wars"); Robert Berner, *Some Licensed Pharmacists Are Starting to Move in on Doctors' Turf*, WALL ST. J., Jan. 28, 1999, at B1. See generally *infra* Part IV.B. (discussing the significant opposition from the medical communities in various states to initiatives to increase pharmacists' authority). Additionally, materials lobbying for increased pharmacist roles in health care have a significant section specifically aimed at allaying the fears of medical societies, and that evidences the seriousness with which the pharmacy community views the medical opposition. See National Association of Chain Drug Stores, *Collaborative Practice Briefing Book*, in

traditional boundaries of the professions comes from concerns about power, autonomy, and economics, these concerns “should fade as professionals increasingly recognize the benefits of sharing both risks and reward as members of an effective health care team.”¹⁸⁷

As this opposition continues to fade and as the role of pharmacists continues to expand in almost every state, pharmacists will be able to exercise independent or dependent prescriptive authority in an increasing number of states. Hopefully the medical community will grow to embrace collaborative practices that provide optimal patient care because in order for the dependent pharmacist prescriber program for ECPs to succeed at increasing access, there must be “effective communication, mutual trust and respect, and common purpose” between pharmacists and physicians.¹⁸⁸ Perhaps, because dependent pharmacist prescribing is implemented on a state-by-state basis, Washington and New Mexico can serve as models to the rest of the states, providing a broad “pilot study” on which evaluators in other states can make informed decisions. Studies of the functioning of dependent pharmacist prescribers in Washington and New Mexico, together with evaluations of the degree to which each state has an expanded role for pharmacists, can help to provide answers that address the concerns of those who oppose dependent pharmacist prescribing, in order to hopefully lead to increased access in the future.

(2) *Political Opposition to Increasing Access to ECPs*

In addition to debate over expanding the role of the pharmacist, there is likely to be opposition to the proposal to expand access to ECPs at all. ECPs have been controversial, and up until recently there was no dedicated product available in the United States. Furthermore, while the FDA, the American College of Obstetricians and Gynecologists, and the court in *Brown-*

COLLABORATIVE DRUG THERAPY MANAGEMENT STATE ADVOCACY PACKET, 332-63 (Cara Woodson Welch, American Society of Health-System Pharmacists, ed., 1999). Some of the opposition by the medical community to pharmacist prescribing may be attributable to a backlash to the expanded authority of physicians assistants and APNs. See Audrey St. Jean Wittenburg, *Obtaining Prescribing Authority for Pharmacists: Lessons Learned*, 52 AM. HEALTH-SYS. PHARMACY 1616 (1995) (noting that there may be “bad blood” resulting from past battles about nursing authority).

187. Webb, *supra* note 131, at 1695.

188. *Id.* (discussing the requirements for successful collaborative practice).

field conclude that ECPs should be classified as contraceptives rather than as abortifacients, this classification continues to be a subject of debate,¹⁸⁹ and abortion, though legal, is opposed vehemently by many people, especially religious groups. However, while controversy around ECPs exists in some areas, others are very receptive to ECPs.¹⁹⁰ The state-by-state nature of this proposal allows increased access to ECPs in areas where communities are receptive to such increased access. While more information about ECPs is disseminated and while a greater understanding of ECPs is developed, at least some women can have more control over their reproductive futures by being able to try to reduce the chance of an unwanted pregnancy. Hopefully, these more progressive states can point the way for increased access in places where ECPs are more controversial.

C. *Alternative Solutions Possible on the Federal Level Are Unlikely to Succeed*

While this paper proposes a state solution to the problem of access to ECPs, there are a few alternative solutions that could be pursued on a federal level: ECPs could be switched from prescription-only status to over-the-counter ("OTC") status; Congress could create a third class of drugs (including among other things ECPs) that would be available only from pharmacies or pharmacists; or Congress could amend the FDCA to allow all pharmacists to prescribe legend drugs and controlled substances. This subsection will discuss the arguments for each of these proposals and compare their effects and likelihood of implementation to the effects and likelihood of implementation of the state-based dependent pharmacist prescriber proposal.

1. The FDA Is Unlikely to Approve OTC Status for ECPs.
The Intermediate Step of Pharmacist Prescribing
between OTC and Prescription Would Mitigate
the Access Problem

The inquiry into whether a drug should be reclassified from prescription-only to OTC status centers around the second prong of the definition of prescription drugs in 21 U.S.C. § 353(b)(1), which provides that

189. *See supra* Part III.B.6.b.

190. *See infra* Part IV.B. (comparing, in part, the attitudes held by different states toward ECPs).

[a] drug intended for use by man which . . . because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug.¹⁹¹

If a drug does not implicate these safety concerns, under the statutory definition, it is not required to be classified as prescription-only. In assessing whether a drug fits the § 503(b)(1)(B) definition requiring prescription-only status, the FDA has developed the following supplementary questions, “Peck’s Principles,” to aid in the inquiry into the prudence of the switch:

1. Does the switch candidate have special toxicity in its class?
2. Does the candidate have a large margin of safety?
3. Does the candidate’s frequency of dosing affect its safe use?
4. Has the candidate’s safety profile been defined at a high dose?
5. Has the candidate been used for a sufficiently long time on the prescription market to enable a full characterization of its safety profile?
6. What is the world-wide marketing experience of the switch candidate?
7. What foreign countries market the candidate OTC? What is its experience in those countries?
8. What do the “use data” (from the National Prescription Audit, the National Drug/Disease Audit, and/or other sources) show?
9. Has a vigorous risk analysis been performed?
10. Has the efficacy literature been reviewed in a way to support the expected usage and labeling of the switch candidate?
11. Is there a full understanding of the pharmacodynamics of the switch candidate?
12. Is the minimally effective dose for the proposed OTC indication known?
13. Have possible drug interactions for the switch candidate been characterized?¹⁹²

191. 21 U.S.C. § 353(b)(1)(a) (1994); see also Peter Barton Hutt, *A Legal Framework for Future Decisions on Transferring Drugs from Prescription to Nonprescription Status*, 37 *FOOD DRUG COSM. L.J.* 427, 433 (1982) (explaining the focus on the second prong). The first prong of the definition of prescription drugs is inapplicable to ECPs because ECPs are not “habit-forming” as explained in § 352. See Ellertson et al., *supra* note 90, at 227 (explaining that ECPs are not addictive).

192. Lance W. Rook, *Listening to Zantac: The Role of Non-prescription Drugs in Health Care Reform and the Federal Tax System*, 62 *TENN. L. REV.* 107, 122-23 (1994) (quoting *Switch Principles Cited by Peck*, NDMA EXECUTIVE NEWSL. (Non-prescription Drug Mfrs. Ass’n, Washington D.C.), Nov. 16, 1990, at 3).

The statutory factors, understood in conjunction with Peck's Principles, provide the framework for analyzing the appropriateness of switching ECPs from prescription-only status to OTC.

Just as the good safety profile of ECPs provides a good argument for enabling ECP access through dependent pharmacist prescribers,¹⁹³ ECPs (and particularly the progestin-only ECPs) may be good candidates for the switch to OTC status, considering the emphasis on safety in the prescription to OTC switch process. The switch of ECPs to OTC status may implicate many of the same concerns as the switch of OCs to OTC status, so this paper's analysis of the potential for the ECP switch will discuss the major factors in the switch while drawing on the discussion of the arguments around the proposal for an OC switch.¹⁹⁴

a) *Toxicity*

An evaluation of the "acute effects" of a drug and a thorough understanding of the general safety and health risks posed by a drug are central to an inquiry into a drug's "toxicity."¹⁹⁵ While ECPs result in some uncomfortable side effects, including nausea and vomiting in some women, this low level of toxicity may be tolerable for a nonprescription medication.¹⁹⁶ Both the Yuzpe regimen and levonorgestrel (progestin) -only regimen have been studied, and the margin of safety and likelihood of a woman experiencing side effects are well documented based on the established doses.¹⁹⁷ The doses do not vary from woman to woman based on individual traits,¹⁹⁸ and even if taken in excess of the designated dose, toxic effects (like vascular and liver disease) from overdose are very unlikely, even if children consume the excess doses.¹⁹⁹ While women need to be aware of the likelihood of minor side effects, it is notable that the FDA has recognized that studies have shown that it is extremely unlikely for any

193. See *supra* Part III.B.5.b.

194. See generally THE PILL: FROM PRESCRIPTION TO OVER THE COUNTER (Sarah E. Samuels & Mark D. Smith eds., 1994) (discussing issues involved in switching OCs to over the counter status).

195. Hutt, *supra* note 191, at 433-34; see Gerald M. Rachanow, *The Switch of Drugs from Prescription to Over-the-Counter Status*, 39 FOOD DRUG COSM. L.J. 201, 204 (1984).

196. See Rachanow, *supra* note 195, at 204 (noting that low level of toxicity is often acceptable even for nonprescription drugs).

197. See, e.g., WHO Task Force on ECPs, *supra* note 12.

198. See Ellertson et al., *supra* note 90, at 227.

199. See Gynetics, PREVEN Package Insert, *supra* note 122, at 17.

serious adverse effects to result from ECP use.²⁰⁰ In addition to the general lack of toxicity to women, the ECPs are not toxic to fetuses carried by women with already established pregnancies.²⁰¹ The move toward nonprescription status of ECPs in other countries indicates that others consider ECPs safe, and while ECPs have not held nonprescription status for long in most of those countries thus far, the experiences in those countries support that belief.²⁰² Furthermore, while chronic toxicity may be of increasing importance in evaluating the prudence of a switch to OTC status,²⁰³ ECPs are unlikely to be taken chronically,²⁰⁴ but even if a woman were to take ECPs frequently, the chronic effects of OCs, from which ECPs are derived, have been studied for a long time, have been well documented, and could provide an upper bound for chronic effects of ECPs.²⁰⁵

Labeling can be sufficient to instruct women about proper administration and about the appropriateness of the regimen for their situation, thereby minimizing toxic effects.²⁰⁶ While ECPs have practically no contraindications, labeling can advise women with contraindications to OCs to consult their doctor before using the product.²⁰⁷ Additionally, labeling the ECPs with a statement encouraging women to take an anti-nausea medication with the ECPs can further lower the incidence of the common side effects.

Concerns about toxicity and the serious nature of long term effects for some women taking OCs is one of the major obstacles to switching OCs themselves to OTC status.²⁰⁸ Because of links between OCs and vascular and liver diseases, opponents to OTC

200. FDA Notice on ECPs, 62 Fed. Reg. at 8610, 8611.

201. See Ellertson et al., *supra* note 90, at 227.

202. See *supra* Part II.B.

203. See Hutt, *supra* note 191, at 434.

204. See *supra* Part III.B.5.e.

205. See generally DRIFE, *supra* note 123 (compiling and discussing the results of risk studies of OCs). The studies on the risks of OCs provide an extreme upper bound for possible risks of frequent use of ECPs because users of OCs necessarily intake a greater number of pills than even a very frequent user of ECPs (which can not effectively be used more than once per menstrual cycle).

206. See Hutt, *supra* note 191, at 434 (indicating that labeling is a way to "reduc[e] the potential for toxicity" of OTC drugs).

207. See Rachanow, *supra* note 195, at 204 (discussing the tolerance for some level of toxicity and side effects as long as the consumers are made aware of the risks).

208. See Diana B. Petitti, *Safety of Birth Control Pills*, in *THE PILL: FROM PRESCRIPTION TO OVER-THE-COUNTER* 77, 79 (Sarah E. Samuels & Mark D. Smith eds., 1994).

status for OCs stress the need for medical involvement in order to screen and monitor patients appropriately, especially when the risk factors needed to screen out high-risk patients cannot be self identified.²⁰⁹ However, since there is debate about the effectiveness of such medical screening to identify women with contraindications and risk factors for use of OCs, proponents of OTC status for OCs assert that if OCs were OTC, women would be screened out from OCs at a similar rate to those screened out currently under the preprescription standard.²¹⁰

Many of these concerns are mitigated in the context of ECPs because the contraindications are fewer, ECPs pose less risk because of the lower frequency of use, and women can largely self identify risk factors.²¹¹ However, the research on ECPs may leave some questions unanswered, including the clear identification of the health risks associated with long term repeated use.²¹² Even though women are unlikely to use ECPs as long term contraception, currently we can only extrapolate from the OC data to approximate those long term risks from repeated use of ECPs. Additionally, while there has been a controlled experiment with women being able to access ECPs through dependent pharmacist prescribers in Washington,²¹³ researchers have not studied the dynamics of OTC availability of ECPs; other countries that currently have ECPs available without a prescription have not had them on nonprescription status for long enough to fully evaluate the policy and safety implications of that regime.²¹⁴

209. *See id.* at 99-100.

210. *See id.* at 101.

211. *See supra* Part III.B.5.a. (discussing the ability of women to self-diagnose); *supra* Part III.B.5.e. (discussing the likely low frequency of ECP use).

212. Although some risk studies have been performed with ECPs, an evaluation of much of the risk information is based on studies of OCs. ECP studies focus mainly on effectiveness and on side effects occurring concurrently with ECP use rather than on long term effects of repeated use. *See, e.g.*, WHO Task Force on ECPs, *supra* note 12; Ho & Kwan, *supra* note 116. The lack of ECP-independent long term risk analysis could implicate Peck Principles 9 and 10. Additionally, the precise mechanism of ECPs is not known, so that might implicate Peck Principle 11. *See supra* text accompanying note 192.

213. *See* Final PATH Report, *supra* note 50.

214. This implicates Peck Principles 5, 6, and 7, involving the length of time of the product on prescription and the length of time the product has been available over the counter in other countries, both of which allow for fuller characterization of the effects. *See supra* text accompanying note 192. This also ties into the concern under the "collateral methods of use" prong about behavioral implications and safety issues resulting from changed incentives.

These unanswered safety concerns may be sufficient to deter the FDA from moving ECPs to OTC status, and instead, to wait for more research. The questions about long term use effects and the potential for adverse drug events when a wider selection of women use the drug may support the compromise position of the dependent pharmacist prescriber model, which can serve as a basis from which easier access to ECPs can be studied more fully. Under the model, more women may have access to the ECPs, but they are prescreened by the pharmacists for potential contraindications. Under dependent pharmacist prescribing, access is increased from the physician prescription status, and researchers can continue to study the effects of ECPs as their use becomes more common. After the pharmaco-dynamics of the ECPs are studied further, the FDA and the public may be more receptive to moving ECPs to OTC because they will be more confident in the absence of long term effects and in the behavioral implications of easy access.

b) *Other Potentiality for Harmful Effects*

Other potentiality for harmful effect includes potential for abuse.²¹⁵ Like every drug, ECPs can be misused, but the likelihood of misuse is low for practical reasons including cost, side effects, and effectiveness.²¹⁶ Additionally, the concerns about drug-drug interactions²¹⁷ are minor in the context of ECPs, which, based on experiences with OCs, may have a somewhat decreased effectiveness if taken concurrently with antibiotics.²¹⁸ Given that many women use OCs as a successful method of birth control for long periods of time without decreased efficacy, it is unlikely that extended use of OCs or ECPs would result in the development of a tolerance among women.²¹⁹ Furthermore, the concern about tampering with ECPs, if ECPs were reclassified as OTC, is no greater than with any other OTC drug.²²⁰

215. See Hutt, *supra* note 191, at 435.

216. See *supra* Part III.B.5.e.

217. See Hutt, *supra* note 191, at 435 (indicating drug interactions as a concern).

218. See DRIFE, *supra* note 123, at 13.

219. See *id.*; see also Hutt, *supra* note 191, at 435 (noting a "potentiality for harmful effect" could include increased tolerance with frequent use so that efficacy declines).

220. See Hutt, *supra* note 191, at 436 (expressing a concern about tampering).

The safety profile of ECPs is strong, especially when a cost-benefit analysis is performed,²²¹ since increasing access to ECPs by making them available OTC will greatly enhance women's control over their reproductive futures and will enable ECPs to be fully integrated into the contraception regime, thereby markedly reducing the incidence of unwanted pregnancies and abortions, while current research indicates that ECPs pose only minor risks to women.²²²

c) *Method of Use and Collateral Measures Necessary to Use*

Despite the lack of some data regarding the results of unlikely scenarios involving ECP use, the safety and toxicity arguments against moving ECPs to OTC status are relatively weak; however the major arguments against ECP switch to OTC status are likely to arise under the "collateral measures" factor of the inquiry. "Congress intended this factor to have the broadest possible scope. It encompasses all aspects of the circumstances under which a drug is used, including broad questions of social policy. There is perhaps no issue involving drug use that cannot properly be brought into consideration under this factor."²²³ The "collateral measures" concerns that arise in the context of the debate about making OCs available OTC include concerns about the efficacy of OCs as a result of self-administration, concerns about the social policy of women's health care, and economic considerations.²²⁴ While the self-treatment, self-care, and economic arguments do not weigh as strongly against switching ECPs to OTC status as do those arguments against switching OCs to OTC, the social policy concerns about promiscuity and sexually transmitted diseases may be strong enough to persuade the FDA to hold off on making ECPs available OTC.

Self-treatment is less of a concern with ECPs than it is with OCs. The efficacy of OCs decreases as incorrect use among women increases, and there is a concern that if OCs are switched to OTC, even more women will use them incorrectly because of lack of counseling in addition to the already existing human falli-

221. See Rachanow, *supra* note 195, at 205 (endorsing a benefit-to-risk ratio analysis for developing a partial understanding of the margin of safety of a candidate for the Prescription to OTC switch).

222. See *supra* Part III.B. (discussing both benefits and risks of increased access to ECPs).

223. Hutt, *supra* note 191, at 436.

224. See generally THE PILL: FROM PRESCRIPTION TO OVER THE COUNTER, *supra* note 194.

bility element.²²⁵ In comparison, ECPs are easy to self administer and do not require long term ongoing care; women easily self-medicate correctly.²²⁶ The directions, two pills immediately and then two pills twelve hours later, are very easy to follow and labeling can sufficiently explain the regimen to the "lay-woman."

Self-care, in terms of general reproductive health, remains a concern with ECPs as it is with OCs. The concern with making OCs available OTC is that women will not see their health provider for a yearly gynecological exam if not required to get a prescription for OCs, thus leading to less early detection of diseases including breast and cervical cancer.²²⁷ Requiring a prescription for ECPs does not serve this same purpose, since women can currently easily get a prescription for ECPs without ever visiting her doctor or getting a pelvic exam.²²⁸ Additionally, women need ECPs only in "emergencies" (by definition), so women will make a separate, independent choice about whether to see a doctor for a gynecological check-up; they will not rely on a future need for ECPs in order to schedule their check-up. The same number of women who currently go to the doctor will continue to go for check-ups, regardless of increased ECP access. Thus, increasing ECP access by making ECPs available over the counter is unlikely to reduce the number of women who see their doctors for routine checkups. Furthermore, requiring a gynecological check-up in order to obtain ECP prescriptions has a great cost because it limits the potentially great effect of ECPs on reducing the number of unintended pregnancies and abortions, while the benefit of increasing the number of women who get a check-up is likely minimal; it is more likely that the women who could benefit from ECPs will just wait and see if they are pregnant rather than incurring the hassle and discomfort of a doctor's appointment and check-up.²²⁹

225. See James Trussell et al., *Efficacy Implications of Making the Pill Available Over the Counter*, in *THE PILL: FROM PRESCRIPTION TO OVER THE COUNTER* 117, 122-23 (Sarah E. Samuels & Mark D. Smith eds., 1994).

226. See Glasier & Baird, *supra* note 21.

227. See Jacqueline Darroch Forrest, *Patterns of Pill Use and Access to Services*, in *THE PILL: FROM PRESCRIPTION TO OVER THE COUNTER* 149, 173-78, 181-84 (Sarah E. Samuels & Mark D. Smith eds., 1994).

228. See *supra* Part II.D.2. (discussing that women can obtain ECP prescriptions without medical exams through the "Dial EC" program).

229. See Blanchard, *supra* note 83, at 239 (explaining that women might be more likely to use ECPs if they did not have to go to the doctor to obtain them); Vicki Brietbart, *The Impact of Patient Experience on Practice: The Acceptability of Emergency Contraceptive Pills in Inner-City Clinics*, 53 *J. AM. MED. WOMEN'S ASS'N* 255,

However, accomplishment of the broader goal of counseling women with regard to reproductive and general health may be impeded by making either OCs or ECPs available OTC.²³⁰ The concern about lack of counseling opportunities regarding ongoing contraception, discussed in the context of dependent pharmacist prescribing,²³¹ is even more acute in the OTC scenario where women would be able to get ECPs without encountering any type of health care provider. However, it may be the prospect of having to face that kind of counseling after a contraceptive failure or mishap that discourages women from going to their health care provider to obtain ECPs when needed. So in fact, when comparing OTC ECPs and ECPs conditioned on a prescription/gynecological check-up, there may be a net gain of making ECPs available OTC, since the increase in the number of women who actually get ECPs when needed and the resultant reduction of the rate of unwanted pregnancies may outweigh the losses from the foregone counseling opportunities. Making ECPs available OTC increases women's autonomy and reproductive control and eliminates the paternalistic counseling and physical examination requirements that likely deter more women than they help. Dependent pharmacist prescribing could be an effective compromise to the counseling concern; women can have relatively easy access to ECPs but still encounter a health care provider who can provide brief counseling or can at least provide a pamphlet or a recommendation to speak with a doctor.²³²

The economic goal of "provid[ing] the best possible medical care for [] divergent population[s] at the least possible cost"²³³ can be well served by switching ECPs to OTC status while keep-

256 (1998) (citing participants in an ECP program suggesting that ECP use/availability could be improved by eliminating the mandatory pelvic exam); Young et al., *supra* note 66, at 147 (citing the requirement of prescriptions/doctor's appointments and the resultant limited accessibility of ECPs as a common reason women choose not to use ECPs); Marie Sharp, *Moring After Pill 'Should Be Freely Available'*, THE SCOTSMAN, July 4, 1998 (citing a study where there were many more unintended pregnancies among women who had to visit their doctor for ECPs, as compared to women who had more ready access, suggesting that women may be disinclined to go to their doctor to get ECPs).

230. See Sarah E. Samuels et al., *Over-the-Counter Birth Control Pills: An Overview*, in THE PILL: FROM PRESCRIPTION TO OVER THE COUNTER 1, 9-11 (Sarah E. Samuels & Mark D. Smith eds., 1994) (discussing concerns about decreased opportunity for counseling about contraception in general if OCs were made available without a prescription).

231. See *supra* Part III.B.5.f.

232. See *supra* Part III.B.5.f.

233. Hutt, *supra* note 191, at 439.

ing OCs on prescription-only status. The economic benefits of keeping OCs on prescription status result from the insurance and Medicaid scheme that increasingly supplements the costs of OCs and the related medical exams for many women, including many poor women.²³⁴ While the yearly requirement of a pelvic exam in order to obtain a prescription for OCs seems paternalistic, it is that illusory "medical necessity" that enables the medical screening consultation to be paid for by some insurance plans and by Medicaid.²³⁵ Although far from all insurance schemes pay for OCs, many women do rely on the insurance/Medicaid supplement, so there is a concern that if OCs became available nonprescription, the tied-in screening may no longer be a medical necessity, so insurance companies may decline to pay for the medical screening and/or the OCs themselves, thereby actually decreasing access to reproductive health care for the very women who cannot afford to pay for it themselves.²³⁶

Regardless of the persuasiveness of this rationale for maintaining the prescription-only status of OCs,²³⁷ these issues are less influential in the context of ECPs. Women are generally not getting their yearly checkups in conjunction with a prescription for emergency contraception, and thus do not need insurance coverage for a consultation that does not occur. As to the ECPs themselves, while most insurance schemes cover prescription drugs, less than a third cover OCs,²³⁸ and certainly many less will cover prescriptions for ECPs. Thus most women in need of ECPs will pay for them themselves regardless of their prescription status, so medical insurance coverage does not provide a persuasive reason to maintain the prescription-only status for ECPs. Additionally, the cost of drugs may decrease after the drug is made available OTC,²³⁹ so that could result in extra sav-

234. See Forrest, *supra* note 227, at 163-83 (discussing that many women obtain subsidized health care in conjunction with a request for OCs).

235. See *id.*; see also *supra* note 75 (discussing insurance coverage).

236. See Samuels et al., *supra* note 230, at 14.

237. See Nancy L. Buc, *The Switch from Prescription to Over the Counter*, in *THE PILL: FROM PRESCRIPTION TO OVER THE COUNTER* 237, 241 (Sarah E. Samuels & Mark D. Smith eds., 1994) (arguing that the "tie-in" to medical care rationale for keeping OCs on prescription-only status is a bad reason to restrict access for everyone).

238. See Stephen W. Schondelmeyer & Judy A. Johnson, *Economic Implications of Switching from Prescription Status*, in *THE PILL: FROM PRESCRIPTION TO OVER THE COUNTER* 189, 229 (Sarah E. Samuels & Mark D. Smith eds., 1994); see also *supra* note 75 (discussing insurance coverage).

239. See Schondelmeyer & Johnson, *supra* note 238, at 228.

ings to women who pay for ECPs themselves. However, to the extent that insurance companies may increase their subsidy for prescription ECPs as they have for OCs in recent years, the dependent pharmacist prescriber model serves both the function of increasing access to a broader spectrum of women than are served by the physician/clinic prescriber model and the function of maintaining prescription status for ECPs so that they may be paid for by insurance companies that cover the particular prescription.

Additionally, the relationship between ECPs and OCs could result in a stronger call for OCs to be made available OTC if ECPs are made available OTC. If ECPs are made available OTC and OCs remain prescription-only, insurance and Medicaid will still cover the OCs and the related medical screening (to the extent that they currently do). However, there is somewhat of an inequity if ECPs are OTC and OCs are prescription-only (since they are chemically identical), and that inequity may lead to a more vocal argument in favor of OCs being made available OTC. If the FDA finally acquiesced and made OCs available OTC, women could lose some of their insurance coverage for reproductive health care as an ultimate effect of ECPs' availability as OTC. In contrast, dependent pharmacist prescribing of ECPs keeps ECPs as prescription-only status, so the proponents of OCs being made available OTC may not be as vocal and there would be less likelihood that women would risk some of their reproductive health coverage.²⁴⁰

The social policy concerns about making ECPs more easily available most strongly implicate concerns about increasing promiscuity based on increased availability of ECPs, about decreasing responsibility for pre-coital and barrier methods of contraception, and thereby about increasing the spread of sexually transmitted diseases. The implication is that because women know that there is an easily available post-coital method of contraception, in the marginal case, they are less likely to take precautions before or during intercourse. In turn this could lead to

240. It is important to note that this paper does not oppose OCs being made available OTC. This section merely discusses some of the economic implications of a switch of either OCs or ECPs to OTC status. To the extent that the economic implications of switching OCs to OTC status have an adverse impact and to the extent that the ECP switch to OTC status might make an OC switch more likely, an ECP switch might precipitate an ultimate, undesirable adverse economic effect. Of course, there are many factors to be taken into account when discussing an OC switch; economic implication is merely one of them.

more unwanted pregnancies, since ECPs are less effective than other contraceptive methods at preventing pregnancy, and it could lead to an increase in the spread of sexually transmitted diseases because of decreasing use of barrier methods of contraception. While there is a small concern that promiscuity and sexually transmitted disease may increase somewhat with very easy access to ECPs, in general (as in the dependent pharmacist prescriber context), cost, side effects, and decreased effectiveness deter women from relying on ECPs as their contraceptive method,²⁴¹ thus easy access to ECPs merely fills a gap in protecting women acting in their regular manner. While studies have shown that women still behave responsibly when they have easy access to ECPs,²⁴² vocal concerns about promiscuity and STDs may be a political barrier to achieving OTC status for ECPs. Additionally, the concern that reproductive health counseling opportunities will be lost if ECPs are made available OTC, resulting in more promiscuity and less responsibility as a result of less guidance, may lead to further public concern. Public sentiment may support these concerns, regardless of their foundation, and that may sway the FDA against OTC status.

Also, the concern about the nature of ECPs would be a political barrier in making ECPs available OTC, just as it is in potential moves to dependent pharmacist prescribing of ECPs.²⁴³ ECPs are still inherently controversial because some people view them as an abortifacient rather than as a method of contraception.²⁴⁴ However, the members of the pro-life movement are skeptical and vocal about their opposition to ECPs as inducing abortions, and this conflict could create a political climate that is unreceptive to moves to make ECPs available OTC.²⁴⁵ However, this opposition may be more strongly concentrated in some areas of the country than others, so a state-based dependent pharmacist prescriber model (rather than a national move to OTC status) may enable a more subtle transition to increased access to ECPs in the states where concerns about social policy implications and concerns about the abortifacient/contraceptive nature of ECPs are minimal enough so that increased access to ECPs will be effective and well received.

241. See *supra* Part III.B.5.e.

242. See Glasier & Baird, *supra* note 21.

243. See *supra* Part III.B.6.b.-c.

244. See *supra* Part III.B.6.b.-c.

245. See *supra* Part III.B.6.b.-c.

Public concerns about the long term safety of repeated ECP use and concerns about economic implications of making ECPs available off prescription, together with concerns about the behavioral and social policy implications of increased access to ECPs (including promiscuity, STDs, availability of counseling and reproductive health care, and the abortifacient/contraception character of ECPs) may make switching ECPs to OTC status a politically unpopular move. Trying to solve the ECP access problem through making ECPs available OTC, rather than by addressing it on the state level, may just deprive all women from increased access because of vocal but localized opposition. While state-based dependent pharmacist prescribers are not as clearly an affirmative statement by the government in favor of ECP access as making them available OTC would be,²⁴⁶ the dependent pharmacist prescriber model enables increased access in areas where the political atmosphere is less hostile to the proposal. Thus, dependent pharmacist prescribing can allow for at least a piecemeal solution to the access problem, and perhaps, it can point the way toward increased access nationwide in the future.

2. The FDA and/or Congress Are Unlikely to Create a Third Class of Drugs That Would Allow Women to Obtain ECPs Directly From a Pharmacy or Pharmacist

a) *In General, the FDA Is Unlikely to Create a Broad Third Class of Drugs That Would Allow Current Prescription-Only Drugs to Be More Accessible*

The FDA has traditionally opposed the creation of any type of intermediate nonprescription class of drugs between prescription and OTC,²⁴⁷ and is thus unlikely to create a federal interme-

246. *See supra* Part II.D.2. (critiquing current access to ECPs partially because letting private individuals control the entire access question can be viewed as a "cop-out" on the part of the government). While the dependent pharmacist prescriber model still relies on individual initiative to create protocols under which access to ECPs would be increased, many state legislatures would have to change their existing laws to accommodate the regime. *See infra* Part IV.B. Certainly, ECPs would be part of such a discussion to change the laws, and in states that make changes in order to allow for dependent pharmacist prescribing of ECPs, state legislatures would knowingly imply an endorsement of the ECP dependent pharmacist prescriber regime, even if they declined to explicitly address the issue in the manner that the FDA would have to address it if ECPs were made available OTC.

247. *See* OTC Drugs, 39 Fed. Reg. 19880, 19881 (1974) (after citing a number of reasons, "[t]he Commissioner therefore categorically rejects the establishment of a third class of drugs at this time"). *See generally* ABOOD & BRUSHWOOD, *supra* note

diate class of pharmacy or pharmacist drugs (whereby drugs are classified as nonprescription but are available from a pharmacy or pharmacist only, respectively)²⁴⁸ merely in order to increase access to ECPs. A third class of drugs can be conceived of in one of two general ways, either as a way to *increase* access to drugs that are currently prescription-only or to *restrict* access to drugs that are currently available OTC. If a third class of drugs was to be created with ECP access in mind, the purpose would be to *increase* availability of drugs that are currently prescription-only by creating either a fixed class (with drugs permanently restricted to sale by pharmacists or pharmacies) or transitional class (as a testing ground for later movement to OTC status). While many of the arguments against a third class of drugs are aimed at preventing a third class from being introduced in order to *restrict* access of drugs that are currently OTC, many of the general arguments against a third class apply even when third class is proposed for the purpose of increasing access to drugs that are currently prescription-only.²⁴⁹

The major arguments against using a third class of drugs include: self-care through nonprescription drugs is a basic and important component of the U.S. health care system; nonprescription drugs are by definition safe and effective without intervention by a health care professional; consumers read drug labels, and self administer safely, and therefore should not be forced to consult a pharmacist; manufacturers should be able to distribute safe and effective drugs conveniently; requiring consumers to buy certain nonprescription drugs only in pharmacies hurts them rather than helps them because the drugs are less convenient and because there is no reason to believe that a clerk in a pharmacy is any better equipped to help consumers than a nonpharmacy clerk; and creating such a third class operates only to create a monopoly that lessens competition, thus likely in-

106, at 84 (citing a 1984 FDA policy statement reaffirming the 1974 FDA rejection of a third class of drugs).

248. A pharmacist class of drugs is “[a] class of drugs available without a prescription but the pharmacist must be involved in a sale.” GAO Report, *supra* note 136, at ch. 2:2. A pharmacist class of drugs is more restrictive than a pharmacy class because while a drug in the pharmacy class is available without a prescription in pharmacies, the pharmacist need not be involved in the sale. *See id.* The traditional conception of a “third class of drugs” is that of the pharmacy class, but a variation on that could be a pharmacist class. *Id.*

249. *See* Gregory M. Fisher, *Third Class of Drugs — A Current View*, 46 FOOD DRUG COSMETIC L.J. 583 (1991).

creasing prices.²⁵⁰ These arguments oppose the proposition that OTC drugs, that are already deemed safe and effective for use by a consumer without the oversight of a health care professional, should be *restricted* to pharmacy or pharmacist sale. They do not address the issue of whether certain drugs that are currently not categorized as safe and effective without the involvement of a health care professional should be made *easier* to obtain.

However, if a third class of drugs was created on a federal level in order to enable some drugs currently classified as prescription to become more *easily* available through pharmacists/pharmacies, even that move could implicate the aforementioned concerns discussed in the context of *restricting* access. Once a third class is created, it might lead current prescription-only drugs to be placed in the third class rather than going directly to OTC status, despite a possible showing that they are safe and effective without involvement of a health care professional; that move would restrict access to the otherwise prescription-to-OTC switchable drugs, rather than increase access, and would thereby implicate the aforementioned concerns about creating a third class that effectively limits drugs that could be OTC.

Additionally, opponents to a third class of drugs argue that the third class serves little purpose beyond those served by the current two class system. Using a third class of drugs to deter abuse may not be effective.²⁵¹ Also, a third class of drugs used to provide extra counseling to consumers may not practically serve that purpose; the GAO report on the drug dispensing systems of 11 countries indicated that in Australia, where some states set pharmacist counseling requirements, the counseling require-

250. See *id.* at 598. The FDA concurs in many of these arguments against a third class —

Restricting the sale of some or all OTC drugs only to pharmacies would decrease the number of outlets where the consumer could purchase OTC products, limit competition, and raise some OTC drug prices, with no attendant public benefit. There is at this time no public health concern that would justify the creation of a third class of drugs to be dispensed only by a pharmacist or in a pharmacy. The “third class of drug” issue at this time is solely an economic issue.

39 Fed. Reg. at 19881. The counter-arguments in favor of a third class of drugs include: pharmacists should be near the sale of all drugs because they have some medical training; pharmacists should be available to counsel consumers regarding switched drugs because they are more potent than other nonprescription drugs and because consumers may not be able to read the labels; and pharmacists exercise better control over the drugs than employees in nonpharmacy stores, which can prevent problems like tampering. See Fisher, *supra* note 249, at 593.

251. See GAO Report, *supra* note 136, at ch. 2:5.

ments are not well followed or well enforced.²⁵² If the goal of the third class is to protect consumer safety because those drugs for which increased access is desired are not safe and effective without instructions on risks and administration, it is questionable as to how effective this third class would be at protecting consumer safety given the questions about the effectiveness and enforceability of counseling. Additionally, it is unclear how a third class of drugs would be treated by insurance; thus it is possible that a third class could have the same detrimental economic effect of lost coverage, similar to those discussed with respect to switching ECPs and OCs from prescription-only to OTC status.²⁵³

Thus, this presents the question of which drugs would be put in the third class. If the abuse prevention and counseling rationales for the creation of a third class do not hold, it seems that, absent an independent drug-specific rationale for placing the drug in the third class, the third class drugs would effectively be a subset of the OTC class but with less access; if the drugs are merely in a subset of OTC, they would thus need to be as safe and effective for use without medical involvement as regular OTC drugs.²⁵⁴ This reinforces the argument for retaining the two class system of drug classification; if drugs are not safe and effective without the involvement of a health care practitioner, they should be classified as prescription, otherwise, they may be classified as OTC.

b) *Although There May Be a Drug-Specific Rationale for Categorizing ECPs in a Third Class, the FDA Is Unlikely to Create a Third Class of Drugs, Reversing a Long Standing Policy of a Two Class Drug System, Merely in Order to Make ECPs More Accessible*

Classifying ECPs as third class drugs may not implicate the general concerns against a third class as strongly as other possible third class drugs might. Creating a third class of drugs, including ECPs, provides *easier* access to a drug currently categorized as

252. See *id.* at chs. 4:1-4:3.

253. See *supra* Part III.C.1.c.

254. The GAO reports that the experience in other countries is such that little increased safety concerns are served by making a drug available only through a pharmacy. See GAO Report, *supra* note 136, at ch. 4. Thus, if there is no real increase in safety from placing drugs in an intermediate class rather than in an OTC class, it seems the drugs in the intermediate class should be no less safe than those in the OTC class.

prescription rather than *restricting* access to a current OTC drug. It would enhance women's ability to self-care and is somewhat less paternalistic than is the current prescription-only regime. A third class, in the case of ECPs, is not intended to protect against abuse, as ECPs are unlikely to be misused,²⁵⁵ so arguments in favor of classifying ECPs in a third class are not undermined by arguments that a third class does not effectively guard against abuse.²⁵⁶

While any attempt to classify ECPs as pharmacist or pharmacy drugs may face political opposition similar to that faced by a possible OTC switch,²⁵⁷ the creation of a pharmacist class for ECPs may hold more promise, since the arguments specifically aimed at the prudence of a pharmacist class parallel many of the arguments against dependent pharmacist prescribing (which are of little import in the ECP context).²⁵⁸ While opponents argue that pharmacists do not have adequate training and expertise to diagnose illness,²⁵⁹ a traditional diagnosis is not required for the dispensing of ECPs, as women know if they have had unprotected intercourse and thus know when ECPs are warranted.²⁶⁰ Characteristics specific to ECPs provide a large measure of protection against misuse regardless of pharmacists involvement.²⁶¹ Pharmacists can be relied upon to provide at least minimal counseling to patients regarding drug administration as evidenced by the Washington State Pilot Project, and administration is so simple that women can and do self administer without involvement from any health care provider.²⁶² Furthermore, while pharma-

255. See *supra* Part III.B.5.e. (explaining that ECPs are unlikely to be misused).

256. See *supra* Part III.C.2.a. (expressing concerns about the effectiveness of a third class at preventing abuse).

257. See *supra* Part III.C.1.c.

258. See *supra* Part III.B. (discussing arguments for and against dependent pharmacist prescribing in the context of ECPs). A pharmacist class is similar to dependent pharmacist prescribing in that the drugs must be obtained directly from the pharmacist. This can be compared to a pharmacy class, where drugs are available only in a pharmacy, but anyone who comes into a pharmacy can purchase them without ever encountering a health care professional; this degree of contact with a health care provider makes the pharmacy class more like the OTC class and makes the pharmacist class more like drugs that are available from dependent pharmacist prescribers.

259. See GAO Report, *supra* note 136, at ch. 1, tbl. 1.1.

260. See *supra* Part III.B.5.a.

261. See GAO Report, *supra* note 136, at ch. 1, tbl. 1.1 (expressing concern that intermediate class cannot guard against misuse). *But see supra* Part III.B.5.e. (explaining that ECPs are unlikely to be misused).

262. See GAO Report, *supra* note 136, at ch. 1, tbl. 1.1 (noting concerns about counseling and self administration). *But see supra* Part III.B.5.a., f. (discussing coun-

cists might want compensation for the time spent counseling, they can be adequately compensated while still lowering the overall cost of access to ECPS.²⁶³

While the arguments for classifying ECPs as a third class drug may be somewhat persuasive, it is unlikely to be done on the federal level. The long standing policy²⁶⁴ against a third class would be very difficult to overcome without a broad-sweeping, very persuasive rationale. This is likely true because the creation of a third class results in reversal of repeated rejection of the idea of a third class after significant study;²⁶⁵ creating a third class at all (even if aimed particularly at one drug) effectively announces that third class classification is a federally sanctioned option, thus encouraging some drug manufacturers to seek third class classification for other drugs for which the arguments in favor of third class status may not be as persuasive. Additionally, the FDA would face a large administrative task of carrying through comprehensive changes to the drug control system,²⁶⁶ and query whether it would be efficient to take on such a task if the third class was targeted at one drug alone or if the value of a third class for drugs in general has not been clearly shown.²⁶⁷

seling); Glasier & Baird, *supra* note 21 (finding that women self-administer ECPs safely). However, dependent pharmacist prescribing provides more checks and balances (than does a third class) to ensure that pharmacists perform the counseling role because of the collaborative nature of the practice. See *supra* Part III.B.5.d.

263. See GAO Report, *supra* note 136, at ch. 1, tbl. 1.1 (noting that pharmacists will want to be compensated for their increased role). But see *supra* Part III.B.2. (discussing that, because of efficiency gains and cost reductions, pharmacists should be able to be so compensated); see also Final PATH Report, *supra* note 50, at 15 (presenting a proposal as to how to compensate pharmacists for their time by charging a \$10 service fee).

264. See OTC Drugs, 39 Fed. Reg. 19880, 19881 (1974) (rejecting a third class); ABOOD & BRUSHWOOD, *supra* note 106, at 84 (citing a 1984 FDA policy statement reaffirming the 1974 FDA rejection of a third class of drugs); GAO Report, *supra* note 136 (finding, in 1995, that the value of a third class has not been proven).

265. See GAO Report, *supra* note 136 (finding, in 1995, that the value of a third class has not been proven).

266. See *id.* at ch. 6 (noting that while the FDA commented that a number of changes would have to be made in order for the United States to adopt a third class of drugs, "[a] comprehensive assessment of all such changes was beyond the scope of GAO's work").

267. See GAO Report, *supra* note 136 (finding, in 1995, that the value of a third class has not been proven). Additionally, it is not entirely clear that the FDA has the authority to establish a third class without an act of Congress. See Fisher, *supra* note 249, at 602-03, in which the author quotes the agency itself, questioning its authority to establish a third class of drugs, as saying,

Under the Federal Food, Drug, and Cosmetic Act ("FDCA") there is no provision for an intermediate class of drugs between OTC and pre-

3. Under the Federal Food, Drug, and Cosmetic Act, the FDA Relies on State Licensure of Practitioners, and This Is Unlikely to Be Changed to Enable Dependent Pharmacist Prescribing Through Federal Law

The proposal of this paper, to allow pharmacists to prescribe ECPs through collaboration with a physician, does not advocate the creation of a class of drugs distinct from prescription-only or OTC, thus dependent pharmacist prescribing is a concept distinct from a nonprescription pharmacy class. Rather, the proposal is to expand the definition of the categories of "providers" in some circumstances to include pharmacists as qualified to write prescriptions for ECPs and to expand the scope of pharmacy practice to include dependent pharmacist prescribing. Under this regime, ECPs retain their status as prescription drugs, but pharmacists, as well as physicians, can prescribe them. Certainly, this is a fine distinction to draw from a pharmacist-only intermediary class of drugs whereby the drugs, though nonprescription, can be obtained only directly from a pharmacist. However, this distinction is important and is acknowledged by the GAO.²⁶⁸

The arguments in favor of enabling dependent pharmacist prescribers through federal law are similar to those in favor of enabling dependent pharmacist prescribing on the state level²⁶⁹ and are likely stronger than the arguments for creating a third class. Particularly, dependent pharmacist prescribers will be more likely to interact and counsel the customer than would pharmacists dealing with a third class drug because the patient, for whom the pharmacist dependently prescribes, must answer specified medical questions and sign a consent form. The involvement of the collaborating physician provides checks and balances to promote compliance. Additionally, with a dependent

scription products. The statutory requirement that a drug either be limited to prescription dispensing or available OTC with adequate directions for use seems to preclude the agency from establishing a class of drugs whose labeling would need to be supplemented by a pharmacist's instructions.

Id. (quoting Letter from Frank Young, Commissioner of Food and Drugs, to Charles M. West, NARD, at 2 (Dec. 1984)).

268. See GAO Report, *supra* note 136, at ch. 5 (differentiating between third class drugs in other countries, independent pharmacist prescribing power in Florida, and dependent pharmacist prescribing authority in a few other states).

269. See *supra* Part III.B. (arguing for state enabled dependent pharmacist prescribers).

pharmacist prescriber, the ECPs retain their prescription status, so they are more likely to be reimbursable through insurance to the same extent as when they were prescription-only from a doctor, so the cost structure is less of a concern.

Despite these arguments in favor of enabling dependent pharmacist prescribers through federal law/regulations, this course is unlikely to be pursued. The FDA has historically relied on state licensure of the pharmacy and medical professions, and is unlikely to take over this entire very detailed area, in part because enabling dependent pharmacist prescribers on the federal level would entail substantial practical and policy changes to the FDA scheme. Currently, the FDCA leaves the states to define who qualifies as a “practitioner licensed by law to administer such [prescription] drug,”²⁷⁰ and in order to enable federal level dependent pharmacist prescribing, the FDCA would need to include pharmacists collaborating with physicians as “practitioners licensed by law to administer such drug.” Arguably, this requires legislation by Congress to preempt state regulation of pharmacy law with regard to determinations both as to whether pharmacists qualify as practitioners and as to the scope of pharmacy practice. The FDA is unlikely to try to influence Congress to take such action because the FDA has been historically averse to explicitly singling out pharmacists from the field of health care practitioners (including APNs, RNs, LVNs, PAs, midwives) as a particular sources of information regarding drug use.²⁷¹ Furthermore, a federal dependent pharmacist prescriber scheme is very similar to the intermediate pharmacist class, so the distinction may not be particularly meaningful to consumers and political constituencies, and because of the similarity between a third class and dependent pharmacist prescribing, an attempt to enable federal level dependent pharmacist prescribing would face many of the same arguments that are levied against a third class.

While there is unlikely to be a federal move to increase access to ECPs through either a third class of drugs or dependent

270. 21 U.S.C. § 353(b)(1)(B) (1994).

271. See Fisher, *supra* note 249, at 600-01 (discussing that the FDA rejected an OTC labeling proposal that stated, “Caution: If pregnant or nursing baby, consult your physician or pharmacist before using this product” and instead included only “physician” and not “physician or pharmacist” for the labeling requirement, and explaining that the FDA declined to explicitly name pharmacists as a particular type of health care professional that a person should consult in the case of an accidental overdose). As already discussed, the FDA has also rejected the creation of a pharmacist class of drugs. See 39 Fed. Reg. 19880; GAO Report, *supra* note 136.

pharmacist prescribing authority, such moves may face fewer obstacles on the state level. Since states already regulate pharmacy law individually, there is an opportunity to enable experimentation and comparison of systems among states in order to determine what kind of system best serves all interests at stake. This "laboratory of the states" approach has been endorsed in other situations.²⁷² Additionally, the political atmospheres in the individual states may make them more receptive to such moves. Since states already regulate pharmacy law, it is much easier for them to make changes in the definition of practitioner and in the scope of the practice of pharmacy; furthermore, some states already have systems in place that pharmacists and physicians could take advantage of to create greater access to ECPs through collaborative agreements. In comparison, federal level enabling of dependent pharmacist prescribing would require the assumption by the FDA of the responsibility for the establishment of complex regulations and for the tremendously detailed administrative monitoring, which the states are already doing or are already equipped to do. Additionally, differences in the state's remaining medical and pharmacy laws make it difficult to create a single guideline for collaboration; dealing with the different health care schemes and authorities in each state should be left to the states, since state administrators are best suited to create a collaborative practice regime that fits within their already existing health care system.

272. Numerous cases have cited Justice Brandeis' dissenting opinion in *New State Ice Co. v. Liebman*, 285 U.S. 262, 311 (1932) (Brandeis, J. dissenting), which explains that "[i]t is one of the happy incidents of the federal system that a single courageous State may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country." See, e.g., *Cruzan v. Missouri Dept. of Health*, 497 U.S. 261, 292 (1990) (O'Connor, J. concurring) (citing Brandeis and explaining that "the more challenging task of crafting appropriate procedures for safeguarding incompetents' liberty interests is entrusted to the 'laboratory' of the States"); see also RICHARD A. POSNER, *OVERCOMING LAW* 107-08 (1995) (endorsing the idea of the laboratory of the States).

D. *State Law Enabled Dependent Pharmacist Prescribing Is in Accord with Federal Law*

1. The Food and Drug Administration Modernization Act of 1997 Arguably Does Not Preempt State-based Initiatives for Dependent Pharmacist Prescribing, and Thus Such Initiatives Should Not Be Rejected Merely Because of a Preference for National Uniformity

One argument in favor of addressing the problem of ECP access on the federal level rather than on the state level is to promote uniformity among the states. Uniform state laws are arguably “needed to protect consumer’s health, assure high quality food [and drugs], and eliminate objectionable trade barriers.”²⁷³ Particularly, *if* (in contrast to our current system) nonprescription drug requirements were to vary from state to state, producers might be required to have multiple manufacturing lines in order to accommodate different state labeling, packaging, composition, or other state specific requirements. This, in turn, might promote needless inefficiency in production and raise the ultimate price of nonprescription drugs for consumers. This could potentially be a serious concern because one of the great health care benefits of nonprescription drugs is that drugs marketed OTC may be priced lower than their prescription-only predecessors. In addition to raising prices, the Senate recognized that “[d]ifferent or additional requirements at the state or local level can work against our national marketplace, confuse consumers, . . . undermine public confidence in our regulatory system and in products important to the public health, and result in divergent public health protection throughout the country.”²⁷⁴

It is this rationale that led to preemption of state regulation of nonprescription drugs in favor of national uniformity, as passed in the FDA Modernization Act of 1997. The FDA Modernization Act added 21 U.S.C. § 379r which says that, unless otherwise provided, states and localities may not establish or continue to enforce any provision regarding nonprescription drugs (those “not subject to the requirements of [21 U.S.C.

273. PETER BARTON HUTT & RICHARD A. MERRILL, *FOOD AND DRUG LAW* 990 (1991) (excerpting Melvin Hinich & Richard Staelin, *Regulation of the U.S. Food Industry*, Appendix, VI Study on Federal Regulation, S. DOC. NO. 14, 96th Cong., 1st Sess. (1978)).

274. S. REP. NO. 105-43 (1997).

§ 353(b)(1)] or [21 U.S.C. § 353(f)(1)(A)]” “that is different from or in addition to, or that is otherwise not identical with, a requirement under this Act [FDCA], the Poison Prevention Packaging Act of 1970, or the Fair Packaging and Labeling Act.”²⁷⁵

This preemption provision is intended to provide national uniformity for requirements including “product manufacture or composition, labeling, advertising, or any other form of public notification or communication”²⁷⁶ with respect to nonprescription drugs. It should not preempt state implementation of dependent pharmacist prescriber laws for ECPs. First, § 379r explicitly refers only to those drugs not subject to § 353(b)(1).²⁷⁷ ECPs are currently prescription drugs subject to § 353(b)(1) and nothing about the dependent pharmacist prescriber proposal alters the prescription-only status of ECPs.²⁷⁸ ECPs are to remain available only by prescription, but states are to expand their § 353(b)(1) definition of “practitioners” to include pharmacists who have formed collaborative drug therapy agreements with physicians. The scope of pharmacy practice would be expanded to include prescribing pursuant to collaborative agreements. Second, § 379r(c)(1) provides that the preemption section “shall not apply to — (A) any State or political subdivision requirement that relates to the practice of pharmacy;”²⁷⁹ which dependent pharmacist prescriber legislation clearly does. Such legislation provides that the practice of pharmacy shall include prescribing certain prescription medications pursuant to a collaborative drug

275. 21 U.S.C. § 379r(a) (Supp. 1997). Section 379r(b) provides an that the FDA may exempt certain states or localities from (a) if their regulation would “(A) protect [] an important public interest that would otherwise be unprotected, including the health and safety of children; (B) would not cause any drug to be in violation of any applicable requirement or prohibition under Federal law; and (C) would not unduly burden interstate commerce.”

276. S. REP. NO. 105-43 (1997).

277. 21 U.S.C. § 379r(a) (Supp. 1997).

278. There might be a very different analysis if a state tried to create a state-based third class of drugs, which would be nonprescription, and thus not subject to § 353(b)(1) and therefore might be included in the national uniformity provision. One of the many reasons that this paper does not propose such a move is that such state moves toward pharmacist classes of nonprescription drugs may be preempted. The object of this paper is to propose a feasible method of increasing access and although the effect of a pharmacist class and of a dependent pharmacist prescribing power is similar, in that women could obtain ECPs from her pharmacist either way, the implications of each choice, at least with regard to preemption and ease of change, may be unique.

279. 21 U.S.C. § 379r(c)(1) (Supp. 1997).

therapy agreement with a physician. This exception is made explicit in § 379r(c)(1)(B) which provides an exception from the federal preemption for “any State or political subdivision requirement that a drug be dispensed only upon the prescription of a practitioner licensed by law to administer such drug.”²⁸⁰ Thus, it is precisely this requirement, drugs being dispensable only on the prescription of a licensed practitioner, that is central to the state creation of a dependent pharmacist prescriber regime for ECPs.

While the text of the national uniformity provision for non-prescription drugs does not prevent state implementation of dependent pharmacist prescribing authority, similarly, the arguments for uniformity are not so persuasive as to prevent states from adopting state-by-state regulations allowing for dependent pharmacist prescribing. The purpose of the national uniformity provision is to prevent states from making it harder to obtain nonprescription drugs and from making it harder for the market to provide nonprescription drugs by imposing additional state requirements on nonprescription drugs and their dispensing beyond those required under federal law or regulation.²⁸¹

States allowing dependent pharmacist prescribing of ECPs do not implicate these concerns. No additional economic burdens, in terms of different packaging or labeling, are imposed on manufacturers of ECPs. The information provided from state to state does not say ECPs are more dangerous than the FDA says they are. The level of health protection throughout the country is maintained since dependent pharmacist prescribing of ECPs together with the good safety profile of ECPs result in women being as safe as they are under current methods of prescription. Although access is increased in some areas, this is not a concern driving the move toward uniformity and such increased access would not “confuse consumers . . . [or] undermine public confidence in our regulatory system.”²⁸² Since neither the text nor the spirit of the national uniformity provision of the FDA Modernization Act of 1997 conflict with or preclude state-based depen-

280. 21 U.S.C. § 379r(c)(1)(B) (Supp. 1997); *see* H. REP. NO. 105-310 (1997) (“This provision [national uniformity] does not apply to any requirement that relates to the practice of pharmacy or any requirement that a drug be dispensed only upon the prescription of a practitioner licensed by law to administer the drug.”).

281. *See* S. REP. NO. 105-43 (1997).

282. *Id.*

dent pharmacist prescribing, such state initiatives should not be preempted by the national uniformity provision.

2. Because Patient Safety Is Protected, ECP Prescriptions Written By Dependent Pharmacist Prescribers Are Valid Prescriptions Under Federal Case Law Despite the Absence of an Ongoing Relationship Between the Patient and the Collaborating Physician and Despite the Lack of a Complete Physical Examination by the Dependent Pharmacist Prescriber.

While the majority of cases that discuss the requirements for valid prescriptions involve doctor defendants who allegedly provide excess quantities of controlled substances or provide prescriptions therefor,²⁸³ a general understanding of the requirements for valid prescriptions can be gleaned from these cases. In order for a prescription to be valid under federal case law, it must be for a legitimate medical purpose and in the course of professional treatment.²⁸⁴ These requirements are intended to help protect the health and safety of patients and to protect the

283. See, e.g., *Webb v. United States*, 249 U.S. 96 (1919) (describing a doctor providing "prescription" "for the purpose of providing the user with morphine sufficient to keep him comfortable by maintaining his customary use"); *United States v. Rosen*, 582 F.2d 1032, 1035 (5th Cir. 1978) (finding that a doctor's prescription of a variety of amphetamines and barbiturates without a legitimate medical purpose and outside the course of the doctor's professional practice to be illegal); *White v. United States*, 399 F.2d 813 (8th Cir. 1968) (finding that a doctor illegally prescribed amphetamines and barbiturates); *De Freese v. United States*, 270 F.2d 730 (5th Cir. 1959) (finding that a doctor and his wife illegally sold Benzedrine (an amphetamine) in bulk without a valid prescription); *Brown v. United States*, 250 F.2d 745, 746-47 (5th Cir. 1958) (finding that the doctor illegally dispensed dextro-amphetamine hydrochloride tablets without a prescription). These cases involve actions under either the FDCA or the Harrison Narcotics Act, but the cases seem to indicate that the requirements for prescriptions are consistent between the acts. See, e.g., *De Freese*, 270 F.2d at 735 n.5 (using an understanding of "prescription" from cases involving the Harrison Narcotics Act in a case under the FDCA). So too, will the cases be treated here.

284. *Webb*, 249 U.S. at 99-100 (finding that a prescription must be issued "in the course of professional treatment"); *Rosen*, 582 F.2d at 1035 (quoting *United States v. Collier*, 478 F.2d 268, 271-72 (5th Cir. 1973), for the proposition that a physician "is expected to prescribe or dispense drugs within the bounds of his professional practice . . . [and] is restricted to dispensing or prescribing drugs in the bona fide treatment of a patient's disease"); *White*, 399 F.2d at 817 (requiring that a prescriber "act[] in the course of professional practice" when prescribing drugs); *Brown*, 250 F.2d at 746-47 (requiring "good faith treatment of patients" and quoting *Webb*, 249 U.S. at 99); see also 21 C.F.R. § 1306.04(a) (West, WESTLAW through Feb. 1, 2000) ("A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.").

public from abuses in the sale of potent prescription drugs.²⁸⁵ Factors that should be taken into account to determine the existence of a valid prescription include the existence of a doctor-patient relationship, a medical examination, the consideration of the individual needs of the patient, and adherence to medical standards for quantity and frequency of drug prescriptions.²⁸⁶

The requirement that prescriptions have a legitimate medical purpose reflects the concern that doctors not become "drug pushers."²⁸⁷ For example, there is no valid prescription for controlled substances if the "prescription" is intended to enable the patient to use the controlled substance for a purpose other than the legitimate medical purpose for which the controlled substance is usually prescribed.²⁸⁸ ECPs are used only to provide post-coital contraception in order to serve the legitimate medical purpose of preventing pregnancy after intercourse. There is no real concern that women would desire ECPs for any purpose other than the post-coital prevention of pregnancy. Since ECPs are not addictive, no ECP prescriptions will be written or filled to "cater to cravings of an addict,"²⁸⁹ nor is there a concern that there will be a black market where drug dealers sell ECPs. This is in marked contrast to the cases where doctors "prescribe" addictive narcotics in order to help a patient maintain his addiction,²⁹⁰ or with the knowledge that the narcotics are to be used by or sold to others for purposes other than addressing a specific weight²⁹¹ or pain problem.²⁹² Thus, there is no risk in dependent

285. *White*, 399 F.2d at 817 (condemning a "prescribing" practice exercised "without regard to the health or safety of the individual to whom the prescription is given"); *De Freese*, 270 F.2d at 735 (explaining that one of the purposes of the prescription provision in section 353(b)(1) of the FDCA was "[t]o protect the public from abuses in the sale of potent prescription drugs"); *Brown*, 250 F.2d at 746-47 (explaining that the purpose of legislation mandating that certain pills "be dispensed only upon written prescription of a practitioner licensed by law to administer such drug . . . is the protection of the people from dangerous products which are shipped in interstate commerce").

286. *Brown*, 250 F.2d at 747 n.2 (upholding the trial court's jury instructions regarding proper considerations for determining whether the defendant dispensed drugs with or without a prescription); *Rosen*, 582 F.2d at 1036 (collecting cases and listing behaviors in prior cases where courts have found the absence of valid prescriptions).

287. *Rosen*, 582 F.2d at 1035.

288. *See id.*

289. *Id.* (citing *Collier*, 478 F.2d at 271-72).

290. *See Webb*, 249 U.S. at 99-100.

291. *See Rosen*, 582 F.2d at 1037-38 (dispensing "weight-reduction" drugs that were clearly not being used for that purpose as evidenced by the frequency of prescription, the quantity prescribed, and the demeanor of the physician).

pharmacist prescribing that ECPs will be prescribed for purposes other than post-coital pregnancy prevention; all such prescriptions will be for a legitimate medical purpose.

ECPs prescribed by dependent pharmacist prescribers are prescribed "in the course of professional treatment" of the patient since the dependent pharmacist prescriber prescribes the ECPs in order to help treat a woman's condition only after developing a prescriber-patient relationship through the taking of relevant medical history.

The requirement of a doctor-patient relationship is better understood as a relationship between the *prescriber* and the patient for whom the drugs are being prescribed. This relationship need not be restricted solely to a doctor if the doctor is not the party prescribing. The vast majority of the cases discussed a *doctor-patient* relationship in particular because 1) the defendants in those cases were doctors accused of providing invalid prescriptions for individuals, about whom they knew basically nothing; and 2) these cases arose before most of the recent expansion of prescribing privileges to individuals other than doctors.²⁹³ The purpose of requiring a doctor-patient relationship is to ensure that the prescriber knows enough about the patient so that she can adequately and safely prescribe drugs for use in treatment.²⁹⁴ Thus, the relationship is important, not because there is an arbitrary desire for patients to have relationships with doctors, but because we want the drugs to be prescribed only by someone who has sufficient knowledge of the patient to protect him from potentially harmful products. Therefore, it is the patient's relationship with the *prescriber* that is of concern. For the prescription of ECPs, it is not vital for the patient to have a relationship with the collaborating doctor because the collaborating doctor is not the actual prescriber. Rather the patient needs to have a sufficient relationship with the dependent pharmacist prescriber,

292. See *De Freese*, 270 F.2d at 731 (dispensing amphetamines in bulk to an individual without a prescription who was "doing a little 'selling'").

293. See, e.g., *Brown*, 250 F.2d at 747 (considering the existence of a *doctor* patient relationship in a case against a doctor-defendant decided in 1958). Prescribing authority for individuals other than physicians, dentists, and veterinarians is relatively recent and still is not widespread in a number of states. See NABP 2000 Survey, *supra* note 107, at 64-69 (detailing prescribing authority for health care practitioners other than physicians, dentists, and veterinarians).

294. See, e.g., *White*, 399 F.2d at 819-20 (allowing expert testimony explaining that a relationship "between a doctor and patient before the doctor prescribes drugs" is necessary "because [the doctor] need[s] to know what is wrong with the patient before [he] can adequately and safely use drugs in the treatment").

since the pharmacist is the party who actually prescribes and is thus in the position to protect patient safety.²⁹⁵ So if the dependent pharmacist prescriber of ECPs develops a relationship with the patient that is sufficient to ensure that the ECPs, if prescribed, would be safe and appropriate, the prescription should be considered valid.

The taking of a patient's medical history, even without a full physical examination, is sufficient to enable the dependent pharmacist prescriber to determine whether ECPs would be safe and appropriate for the patient, and thus enable the dependent pharmacist prescriber to safely and validly prescribe ECPs.²⁹⁶ In general, a physical examination may be an important factor in a valid prescription because the prescriber must "know what is wrong with the patient before [the prescriber] can adequately and safely use drugs in treatment."²⁹⁷ It is important that the prescriber be able to "consider the individual needs of the person to whom he [prescribed or] dispensed the drug."²⁹⁸ The Clinton Administration's Initiative to Protect Consumers Buying Prescription Drugs Over the Internet explains that one of the traditional "safeguards to protect consumers against [the] unsafe use of drugs" is the requirement that valid, "new prescriptions be issued only after a physical exam."²⁹⁹ Since the need for ECPs is largely self-diagnosed³⁰⁰ and ECPs have a good safety profile,³⁰¹ a patient's medical history with information about specific risk factors provides sufficient knowledge to make an informed decision about whether ECPs are safe and appropriate for the particular requesting woman. A full physical examination is not necessary. Thus, the taking of a medical history effectively enables the dependent pharmacist prescriber to have "examined" the patient to the extent necessary for a determination of the safety of prescribing ECPs, thus meeting the purpose for which the physical examination factor is considered. Sufficient knowledge of a patient

295. If prescriptions are only valid when the patient has a relationship with a doctor, no APN or PA could write a valid prescription even in states that allow them prescriptive authority. Certainly, the doctor-patient relationship requirement should not be construed so narrowly as to invalidate all of those prescriptions.

296. See *supra* note 104 (listing recommended inquiries by a pharmacist into a woman's medical history prior to prescribing and dispensing ECPs).

297. *White*, 399 F.2d at 819-20 (allowing this expert testimony as to the necessary doctor-patient relationship for drug prescribing).

298. *Brown*, 250 F.2d at 747.

299. Internet Prescription Initiative, *supra* note 42, at ¶3.

300. See *supra* Part III.B.5.a.

301. See *supra* Part III.B.5.b.

that allows a determination of the safety and appropriateness of treatment fulfills the valid prescription requirement of a prescriber-patient relationship pursuant to a sufficient medical exam.

The prescriber-patient relationships, as discussed above, and the level of patient safety that results, significantly exceed the prescriber-patient relationships and safety precautions taken in the cases where courts found a valid prescription to be lacking. In most of the relevant cases discussing invalid prescriptions, the doctor did not even take medical histories of the requesting patient.³⁰² The court in *White* repeatedly mentioned that the doctor failed to make any inquiries into the health of the patient, and indicated that such a failure showed that no real doctor-patient relationship was created, thus no valid prescription could be written.³⁰³ The courts seem to be driven largely by concern for patient safety. The opinions evince the understanding that if a drug is available as prescription-only, then it is not likely to be safe, effective, and appropriate without the involvement of a medical professional. If the relevant prescribing medical professional abdicates his responsibility for ensuring patient safety by declining to even inquire about his patient's health, we cannot have confidence that the safety and benefit of the patients is being protected.³⁰⁴ Dependent pharmacist prescribing of ECPs does not implicate these concerns because the medical inquiries required under the dependent pharmacist prescriber model demonstrate concern for patient safety and drug appropriateness, and effectively protect it. Patients are not endangered by the lack of a full physical examination; rather they are screened by the medical inquiries, and those inquiries result in a level of patient safety significantly higher than the level of patient safety in cases where prescriptions were found to be invalid.

Similarly, the absence of a full physical examination in dependent pharmacist prescribing of ECPs does not implicate the same concerns expressed by the White House and the FDA regarding the lack of a physical examination in the context of In-

302. See, e.g., *Rosen*, 582 F.2d at n.7 ("No medical history of the patient was taken."); *De Freese* 270 F.2d at 732 ("No one made a physical examination of him or asked him any questions about his medical history.").

303. *White*, 399 F.2d at 814, 818 (explaining twice that the court views the doctor-defendant's admission that the doctor "asked no questions concerning the state of [the patient's] health" as the doctor "conced[ing] that none [physician-patient relationship] existed as to the [particular prescription] transaction").

304. See, e.g., *Rosen*, 582 F.2d at 1035; *White*, 399 F.2d at 817-18.

ternet prescribing. The lack of physical examination in the context of prescribing Internet pharmacies poses risks because “[c]onsumers . . . are at risk for adverse effects from inappropriately prescribed medications, dangerous drug interactions, or contaminated drugs, [and because] . . . the potential for serious abuse exists.”³⁰⁵ In contrast, the lack of a full physical examination in dependent pharmacist prescribing does not pose these risks. Adverse drug events are very unlikely with ECPs,³⁰⁶ it is easy to determine whether an ECP prescription is appropriate,³⁰⁷ there are no known major drug interaction concerns with ECPs,³⁰⁸ and there is little risk of ECP abuse.³⁰⁹ Furthermore, the initiative is aimed at “fly-by-night Internet pharmacies” that have “physicians who prescribe drugs without taking a consumer’s medical history or checking for potential drug interactions.”³¹⁰ Dependent pharmacist prescribers are not “fly-by-night” prescribers; rather they must meet certain minimum requirements and their collaborative protocols³¹¹ must be approved by state pharmacy and medical administrators. Furthermore, the dependent pharmacist prescriber model certainly meets the minimum standards of a medical history check, the absence of which is one of the driving concerns in the Internet pharmacy context.

Although the cases discuss the prescriber’s physical examination of the patient as a factor in determining whether there is a valid prescription, none find it determinative. Rather the cases indicate that the absence of a physical examination, together with other factors (the most important of which is protection of patient safety), led the courts to the conclusions that valid prescriptions were lacking. For example, the court in *White* found that there was no bona fide doctor-patient relationship and thus no valid prescription. However, this determination was based not only on the absence of a medical examination and the lack of an inquiry into the patient’s health, but also pursuant to a finding

305. Internet Prescription Initiative, *supra* note 42, at ¶4.

306. *See supra* Part III.B.5.b.

307. *See supra* Part III.B.5.a.

308. *See supra* Part III.B.5.b.

309. *See supra* Part III.B.5.e.

310. Internet Prescription Initiative, *supra* note 42, at ¶¶4-5.

311. Minimum requirements for pharmacists to qualify as dependant pharmacist prescribers and minimum requirements for collaborative protocols are set by the state boards of pharmacy and thus vary from state to state. *See infra* Part IV. (discussing common requirements of dependent pharmacist prescribers and analyzing the requirements of specific states).

that there was no logical relationship between the drugs prescribed and the patient's alleged problem. The doctor "peddle[d] prescriptions without regard to the health and safety of the individual to whom the prescription is given[.]"³¹² Similarly, while there were no physical examinations in *United States v. Warren*³¹³ and *United States v. Brandenburg*,³¹⁴ both of those cases involved the prescription of an excessively large quantity of controlled substances where there was no legitimate relationship between the drugs prescribed and the alleged condition to be treated. Furthermore, in *Warren*, the doctor knew that the patient was delivering the drugs to others, and in *Brandenburg*, the physician prescribed controlled drugs much more frequently than would be consistent with legitimate medical treatment. The court in *Rosen* lists a number of factors that should be taken into account when evaluating a prescriber's behavior and the only one implicated by dependent pharmacist prescribing is that no physical examination is given.³¹⁵ Dependent pharmacist prescribers do not prescribe ECPs in excess quantities or with an understanding that the ECPs will be resold, and the ECPs are prescribed with the patient's health and safety in mind, only for the legitimate medical purpose of post-coital pregnancy prevention. Although there is no full physical examination in dependent pharmacist prescribing of ECPs, as described above, the medical history taken by the dependent pharmacist prescriber of ECPs effectively accomplishes the patient protection purpose of the physical examination requirement.

Thus, ECP prescriptions provided by dependent pharmacist prescribers should be considered valid under federal case law because they meet both the text and the purpose of the valid pre-

312. *White*, 399 F.2d at 817.

313. 453 F.2d 738 (2d Cir. 1972)

314. 155 F.2d 110 (3d Cir. 1946).

315. Other factors include:

- (1) An inordinately large quantity of controlled substances was prescribed.
- (2) Large numbers of prescriptions were issued.
- (3) No physical examination was given.
- (4) The physician warned the patient to fill prescriptions at different drug stores.
- (5) The physician issued prescriptions to a patient known to be delivering the drugs to others.
- (6) The physician prescribed controlled drugs at intervals inconsistent with legitimate medical treatment.
- (7) The physician involved used street slang rather than medical terminology for the drugs prescribed.
- (8) There was no logical relationship between the drugs prescribed and treatment of the condition allegedly existing.
- (9) The physician wrote more than one prescription on occasions in order to spread them out.

Rosen, 582 F.2d at 1036 (citations omitted) (collecting cases with each factor).

scription requirements. ECPs prescribed by dependent pharmacist prescribers will only be prescribed for a legitimate medical purpose since, unlike narcotics, ECPs do not have a black market of addicts who could have cravings for ECPs. Dependent pharmacist prescriptions of ECPs are made in the course of professional treatment because the prescriptions are written only by a prescriber who has developed a prescriber-patient relationship with the patient. The medical history inquiries are sufficient to inform the prescriber of the safety and appropriateness of ECPs for the individual woman. A patient relationship with the collaborating physician is unnecessary because the collaborating physician is not acting as the actual decisionmaking prescriber. A full physical examination of the patient by the dependent pharmacist prescriber is unnecessary because through medical history inquiries, the dependent pharmacist prescriber can obtain information about the patient that is sufficient to enable the prescriber to determine whether the ECPs are safe and appropriate. Thus, ECP prescriptions written by dependent pharmacist prescribers should be considered valid under federal case law because there is a prescriber-patient relationship based on "examination" of a patient's relevant medical history that is sufficient to enable the dependent pharmacist prescriber to protect patient safety.

IV. IMPLEMENTING PHARMACIST PRESCRIBING AUTHORITY FOR ECPs: A STATE LAW SURVEY

Pharmacies are regulated predominantly by state law,³¹⁶ as the FDCA effectively delegates to the states the regulation of who may practice pharmacy and of how pharmacy is practiced. Additionally, states are delegated the power and responsibility of determining which health care professionals qualify as "practi-

316. See *ABOOD & BRUSHWOOD*, *supra* note 106, at 209-27.

Although the states are empowered to regulate the practice of the professions directly, the federal government may indirectly regulate professional practice in two significant ways. First, the federal government regulates the drug product and correspondingly attaches requirements to the product that a practitioner can meet only by behaving in a particular way. Second, the federal government may establish conditions for participation in programs that it funds (or partially funds), requiring states to accept the conditions if they wish to continue receiving federal funds.

Id. at 221; *see, e.g., supra* Part III.B.5.a. (discussing OBRA '90, which is an example of a federal program with conditional funds).

tioners" and thus have prescriptive authority.³¹⁷ Thus, we look to state pharmacy law to determine whether the scope of pharmacists' authority includes, or could include with forthcoming alteration, dependent pharmacist prescribing of ECPs under collaborative agreements between pharmacists and physicians.

A. *Background on Pharmacist's Scope of Practice*

The pharmacist's traditional role under state law is to dispense drugs in accordance with prescriptions from health care practitioners; for example, New York law defines the "practice of pharmacy" as "the preparing, compounding, preserving, or the dispensing of drugs, medicines and therapeutic devices on the basis of prescriptions or other legal authority."³¹⁸

1. Collaboration Between Physicians and Pharmacists

To the extent that states allow pharmacists to have some authority beyond the traditional "dispensing" role, it is usually pursuant to collaborative agreements with physicians.³¹⁹ Before

317. Under the Durham-Humphrey Amendment to the FDCA, §503(b)(1) of the FDCA provides that legend drugs may be prescribed by a "practitioner licensed by law to administer such drug." 21 U.S.C. § 353(b)(1) (1994). Before the Durham-Humphrey Amendments, the FDCA specifically referenced "physician, dentist, or veterinarian." 9 Fed. Reg. 12, 255 (1944). While both the House and Senate reports acknowledge the change in language, neither actually discusses a reason for the language change. See H.R. REP. NO. 82-700, at 2-3, 15 (1951); S. REP. NO. 82-946, at 8, 12 (1951). Although it appears that there was not a specific reason in the legislative history for the language change, the broader language of the Durham-Humphrey Amendment has the important consequence of enabling broader definitions of "practitioner," thus enabling prescribers in addition to merely physicians, dentists, or veterinarians. See Nuzzo, *supra* note 87, at 41-42.

The federal statute, by merely referring to "practitioners licensed by law" leaves ambiguity which the states, to whom licensing and regulation of health care professionals is reserved, fill in. Since health care practitioners are licensed under state law, it is the states that decide which type of health care professionals qualify as "practitioners" and thus have prescriptive authority. See ABOOD & BRUSHWOOD, *supra* note 106, at 85; see also *United States v. Shock*, 379 F.2d 29 (8th Cir. 1967) (looking to state law to determine whether a chiropractor was a practitioner licensed to prescribe drugs). As long as there is no conflict between the federal and state law, states have reserved power under the 10th amendment to regulate in the area. Thus, when state laws and regulations license certain classes of individuals to prescribe, they are doing so pursuant to reserved authority, and such laws and regulations work in concert and are complementary to the federal scheme.

318. N.Y. EDUC. LAW § 6801 (LEXIS through 1999). See generally ACCP Position Statement, *supra* note 70, at 321 (providing a historical discussion of the pharmacist's role).

319. See *infra* Part IV.A.2. (discussing the ways in which the pharmacist's role is being expanded).

discussing the role of collaboration in expanding the role of pharmacists into nontraditional, service-oriented roles, it is important to recognize that some physician-pharmacist collaboration already exists.³²⁰

Even within the traditional scope of pharmacy practice there is *de facto* collaboration between physicians and pharmacists in every state; a hospital physician may evaluate a patient, make a diagnosis, and before writing the final prescription, the physician may check with the hospital pharmacist to make sure that the pharmacist also considers the drug the physician plans to prescribe as among the most effective and least costly. The physician may ask the pharmacist about the pharmacist's other experiences with the particular drug and may inquire about side effects and cost information. If health care providers have good working relationships, they may "collaborate" by discussing a patient's medical care, merely because of a trusting relationship.

However, the kind of collaboration of concern in this paper is *de jure* collaboration, whereby the law allows for the expansion of the pharmacist's authority beyond mere dispensing and into the larger patient-service role under pharmacist-physician protocols that provide for the expanded authority. Certainly, no law-authorized collaborative role expansion will have any effect unless physicians and pharmacists work together, but if pharmacists' authority is legally expanded, pharmacists have the opportunity, if they so desire, to collaborate; thus, with *de jure* collaboration, pharmacists can participate in the health care service-providing profession in ways beyond those permissible in the *de facto* collaboration situation, where a physician with a good working relationship with a pharmacist merely consults that particular pharmacist about questions regarding drugs.

2. Prescribing Authority Versus Administration, Substitution, and Drug Therapy Management Authority

Although very few states include pharmacists as licensed prescribers,³²¹ a number of states have expanded the role of

320. See Galt, *supra* note 2, at 1697-98 ("Pharmacists today — particularly employees of hospitals and organized health systems — may already be in collaborative practice arrangements without realizing it. . . . This is considered routine practice by many pharmacists.").

321. In fact, pharmacists have independent prescriptive authority only in Florida, and that authority is limited to prescribing drugs on a limited formulary. See *infra* Part IV.B. (discussing the individual states' laws).

pharmacists beyond merely dispensing medications. The expanded authority in a given state, based on legally authorized collaboration between pharmacists and physicians, may include one or more of the following: 1) the administration of immunizations/vaccines; 2) substitution power for prescribed drugs or some degree of selection power of particular drugs for certain conditions; and 3) patient-specific or general drug therapy management.

However, calling these types of activities "prescriptive" authority may be somewhat of a misnomer. Traditional "prescribing" contemplates the making of a diagnosis; it involves the assessment/evaluation of a patient by the prescriber and the initiation and authorization of an order for medication based on the diagnosis.³²²

In the administration of vaccines and immunizations, the pharmacist acts under a standing "prescription" from the physician and is not making a "diagnostic-type" decision himself; the pharmacist merely "gives the drug directly to the patient" pursuant to the standing order.³²³ Substitution or selection power of drugs enables a pharmacist to either substitute a therapeutically/chemically identical (but usually less costly) drug for the drug prescribed by the physician or to select an appropriate drug based on the physician's diagnosis and guidelines.³²⁴

A health care professional engaging in "drug therapy management," may monitor, modify, continue, and/or discontinue ongoing drug therapy.³²⁵ Although drug therapy management

322. See Webb, *supra* note 131, at 1693; C. Richard Talley, *Pharmacist Prescribing*, 52 AM. J. HEALTH-SYS. PHARMACY 1635, 1635 (1995).

323. ACCP Position Statement, *supra* note 70, at 327; see NABP 2000 Survey, *supra* note 107, at 82-83 (indicating in which states pharmacists may administer drugs).

324. See ABOOD & BRUSHWOOD, *supra* note 106, at 359-60; see NABP 2000 Survey, *supra* note 107, at 50-51 (detailing state substitution and drug product selection laws).

325. "Monitor" means that "[o]nce drug therapy is initiated, the clinician evaluates response, adverse effects, therapeutic outcomes, and adherence to determine if the drug, dose, or dosage schedule can be continued or needs to be modified." ACCP Position Statement, *supra* note 70, at 327. "Continue" means that "[a]fter monitoring the current drug therapy of a patient, the clinician decides to renew or continue the same drug, dose, and dosage schedule." *Id.* "Modify" means that "[a]fter monitoring a patient's drug therapy, the clinician decides to make an adjustment in dose and/or dosage schedule or may add, discontinue or change drug therapy." *Id.*

In a few states, drug therapy management includes the ability to "initiate" drug therapy. "Initiate" means that "[a]fter selecting the best drug therapy for an individ-

involves the health care professional evaluating the patient and making a determination of how to proceed based on that evaluation, the health care professional is acting pursuant to clear guidelines, criteria, and procedures dictated by the supervising physician, as laid out in the protocol. This expanded role for health care professionals, including pharmacists, contemplates that a patient will first see her doctor, the doctor will make an evaluation and diagnosis of the patient's condition/disease, and the doctor may (if the patient agrees) refer the patient to the collaborating health care professional, who will then monitor the patient and alter the drug regimen based on the protocol or the collaborating health care professional does not make the diagnosis, nor does she initiate or authorize drug treatment that is not already effectively ordered for the patient by the doctor under the protocol.³²⁶

Drug therapy *management* (including monitoring, modifying, and continuing power) can be contrasted with dependent pharmacist *prescribing*, in which the health care professional makes her own initial evaluation of the patient, without the collaborating doctor first examining and diagnosing the patient;³²⁷ then based on the health care professional's evaluation and diagnosis (which itself is guided and informed by the protocol), the

ual patient, the clinician also determines the most appropriate initial dose and dosage schedule and writes an order or prescription." *Id.* Note that "initiating" authority actually allows the pharmacist/clinician to write a prescription, rather than just follow set orders; thus terming "prescriptive" drug therapy management that involves "initiation" is more accurate than calling the remainder of the drug therapy management activities "prescriptive." However, most states do not include initiation as part of their collaborative drug therapy management authorities for pharmacists. Additionally, even states that allow for initiation as part of drug therapy often limit this power with other restrictions, which restrictions prevent the state pharmacists from exercising Washington model dependent pharmacist prescribing. For the purposes of this paper, drug therapy management authority will refer to monitoring, modifying, and continuing of drug therapy, but not to initiating; initiating, where applicable, will be discussed separately and state specific limitations on that "initiation" will be described. This paper distinguishes between mere drug therapy management and pharmacist prescribing, and state defined "initiation" power may refer to either.

326. See ACCP Position Statement, *supra* note 70, at 327 (discussing the collaborative drug therapy management process).

327. For the purposes of this paper, a narrow conception of dependent pharmacist prescribing is taken in order to differentiate between the varying degrees of authority of pharmacists engaged in drug therapy management and dependent pharmacist prescribing. This difference is key to evaluating and comparing the scope of authority in the various states. Recall that despite these characteristics of dependent pharmacist prescribing, prescriptions written pursuant to this authority are valid prescriptions under federal case law. See *supra* Part III.D.2.

health care professional herself initiates and orders the drug treatment based on prescriptive authority delegated to her by the physician pursuant to the protocol.³²⁸ This prescriptive authority is “dependent” because the health care professional’s authority to order medication based on the professional’s own evaluation and diagnosis is derived from, and thus is “dependent” on, the collaborating physician’s own authority to authorize such a prescription, which the collaborating physician has delegated to the health care professional in accordance with the written protocol.³²⁹

It should be noted that, because a health care professional exercising dependent prescribing power evaluates, diagnoses, and orders medication for a patient without simultaneous input from the collaborating physician (other than from the protocol), dependent prescribing power does not require the patient to have an established and ongoing relationship with the collaborating physician; it is sufficient for the purposes of creating a valid prescription for the patient to have a relationship with the dependent pharmacist prescriber so that the prescriber can determine whether the ECP prescription would be safe and appropriate.³³⁰ A number of limitations on drug therapy management make it merely a lesser form of dependent prescribing. In general, drug therapy management requires an established and ongoing patient relationship with the collaborating physician, while dependent prescribing does not. Additionally, in most drug therapy management regimes, the collaborating pharmacist cannot exercise “prescriptive”/“initiative” power,³³¹ she can only modify a drug regime already prescribed by the collaborating physician. A number of other state-by-state differences will be discussed in Part IV.B.

While administration, substitution, and drug therapy management are broad powers in some states for pharmacists, they are not “prescriptive” since they still depend on the physician to make the patient evaluation and diagnosis; the pharmacist merely is enabled to have greater input about the particular drugs, about which pharmacists have a particular expertise.

328. See *supra* note 2 and accompanying text (explaining dependent pharmacist prescribing).

329. See *supra* note 2 and accompanying text.

330. See *supra* Part III.D.2. (explaining the extent to which a prescriber-patient relationship is required for a prescription to be valid under federal case law).

331. See *supra* note 325 (providing terminology definitions).

However, the expansion of the pharmacists' roles in some states to incorporate administration, substitution, and drug therapy management indicates willingness on the part of these states to allow for collaboration between physicians and pharmacists in order to expand the role of pharmacists beyond the very rigid "product" oriented dispensing role to more of a "service" oriented role.³³² These approaches, viewing the pharmacist as a valued health care professional who can contribute to the overall effectiveness and efficiency of the health care system, may be steps toward an even greater role for pharmacists that might eventually enable pharmacists in these states to exercise dependent prescribing authority of the kind in Washington and New Mexico, whereby even a retail pharmacist could prescribe ECPs for a women in his/her pharmacy if appropriate for that woman, even if that woman has no contact with the collaborating doctor.

B. *Analysis of State Pharmacist Prescribing Laws*

This section proposes that the Washington law and rules be used as model for dependent pharmacist prescribing of ECPs, and it is against that model that all other states' collaborative practices are compared.

Characteristics of the Washington model that make it ideal for dependent pharmacist prescribing of ECPs include that it is not limited to institutional settings, it does not require additional pharmacist training, it does not require the patient to have an ongoing relationship with the collaborating physician, it does not require the protocols to be either disease or patient-specific, and the scope of practice allows for pharmacists to initiate/prescribe treatment without the patient consulting the doctor.

Collaborative authority in all other states is more restrictive in one or more of the above five key characteristics. New Mexico is the closest to the Washington model; New Mexico requires additional education for dependent pharmacist prescribers, but oth-

332. States vary in the legal source of authority for pharmacist prescribing/collaborative powers, in the requirements for those prescribing pharmacists, and in the settings and situations in which pharmacists can prescribe. Legal authority for expanded practice is derived typically from the state's definition of "practitioner" or from the state law definition of "practice of pharmacy" in conjunction with either other code sections elaborating on the roles listed as part of the practice or pharmacy and/or with administrative rules interpreting the statute. The source and scope of the pharmacist prescribing power or expanded authority in different states leads to varying levels of authority for the pharmacists, and consequently, to varied likelihoods of success of a move toward dependent pharmacist prescribers.

erwise, pharmacists can exercise the Washington model dependent pharmacist prescribing of ECPs.

Restrictions on the scope of "collaborative drug therapy management" ("CDTM") in all other states prevent pharmacists in those states from being able to exercise Washington model dependent pharmacist prescribing. While the details generally vary from state to state, one characteristic common in all states (other than Washington and New Mexico) that precludes the Washington model dependent pharmacist prescribing is the requirement that the patient have an established and ongoing relationship with the collaborating physician. As to the other characteristics, states tend to rein in pharmacist authority by being liberal on some issues and restrictive on others. For example, pharmacists in North Dakota have a broad scope of collaborative authority, including initiation of treatment, but they can only exercise this power in institutional settings. In comparison, Ohio pharmacists can exercise collaborative authority in all settings, but their protocols must be patient-specific and the scope of their practice is very narrow (modification only after a reasonable attempt to consult and confer with the collaborating doctor, and no initiation). Another model is the Mississippi model of "disease state management" ("DSM") where pharmacists in any setting can exercise very broad powers for the collaborating doctor's patients with a particular disease state, but the pharmacists must have significant extra education and must become credentialed in the particular disease state (like diabetes). There are numerous other permutations involving the issues of setting, pharmacist education, patient/disease specificity, and scope of practice authority, but each permutation carefully limits the expansion of pharmacists' powers. The issue of collaborative practice is a source of great debate in many of the states that have yet to implement any type of collaborative authority for pharmacists.

While there is a trend toward expansion of the pharmacist's role into collaborative practice, most states are unlikely to expand pharmacists authority following the Washington model; some have indicated an interest in the Mississippi model. However, collaborative practice is relatively new in a number of states, so there is an inclination to wait and see how that degree of expanded authority is received and exercised before the state considers expanding pharmacists' practice any further. With more time and experience with collaborative practice, and with greater participation of dependent pharmacist prescribers in

Washington and New Mexico, states with some expanded pharmacist authority may consider further expansion toward the Washington model in the future.

This section provides detail on the Washington model. Additionally, this section discusses a few other states as examples of the varied status of pharmacist prescriptive power throughout the country. This analysis attempts to: 1) cite the relevant code/rule language that serves as the basis for the expanded power; 2) describe the scope and context of the expanded power, comparing the characteristics to Washington; 3) explain whether the current law could be used to increase access to ECPs in a manner similar to this paper's proposal; and 4) provide insight into the actual functioning of the expanded power, including where possible, assessments of the likelihood of further expansion of both pharmacist power in general (toward the Washington model of dependent pharmacist prescribing) and access to ECPs. Furthermore, a chart in Appendix A provides statutory details for numerous states.³³³ The appended chart is intended to help activists in each state to understand the current status and trends regarding the possibility of dependent pharmacist prescribing of ECPs in their state, so as to provide a starting place for change.

1. Washington: The Model for State Pharmacy Laws Allowing Dependent Pharmacist Prescribing

- a) *Description of the Washington Model*

Washington is the paradigmatic example of a state that enables its pharmacists to exercise dependent prescribing authority. It was pursuant to this authority that the Washington State Pilot Project, on which this paper is based, was able to implement a dependent pharmacist prescriber program for ECPs.³³⁴

Pharmacists in Washington can and do create collaborative agreements with physicians pursuant to which they can prescribe drugs. The legal authority for this power is derived from the Washington Revised Code § 18.64.011, which in (10), defines "pharmacist" to be "a person licensed . . . to engage in the practice of pharmacy[.]" and which in (11), defines the "practice of

333. States surveyed include those where background materials indicated that the state has provided pharmacists with expanded privileges. See generally NABP 2000 Survey, *supra* note 107, at 66-69; HEALTH POLICY TRACKING SERVICE, ISSUE BRIEF: SCOPE OF PRACTICE/PRESRIPTIVE PRIVILEGES 6, 14 (1999); Final PATH Report, *supra* note 50, at 10-11; Flanagan, *supra* note 70.

334. See Final PATH Report, *supra* note 50.

pharmacy” to include “the *initiating* or modifying of drug therapy in accordance with written guidelines or protocols previously established and approved for his or her practice by a practitioner authorized to prescribe drugs[.]”³³⁵ The Washington state rules interpreting the scope of “initiating” allow for dependent pharmacist prescribing.³³⁶

The enabling regulations for this section of the statute explain that the prescribing power of the pharmacist requires a that a written guideline or protocol, approved by a practitioner, be filed with the State Board of Pharmacy.³³⁷ According to the Washington Administrative Code § 246-863-100, the written guideline or protocol, which cannot remain in effect for longer than two years, must include the following: a statement regarding the “types of diseases, drugs, or drug categories involved[;]” an explanation of the scope of prescriptive authority (initiating or modifying); a statement of the procedures and decisionmaking criteria for the pharmacist to follow when making prescribing decisions; and a statement of general procedures to be followed ancillary to the prescriptive power, including documentation and communication with the authorizing practitioner.³³⁸

The authorizing practitioner must be actively practicing, and the “authority granted must be within the scope of the practitioner’s current practice.”³³⁹ This authority is not restricted to pharmacists practicing in retail settings,³⁴⁰ is not restricted to a particular drug or disease, nor does it require additional training on the part of the pharmacists (unless specifically stated in the protocol).³⁴¹ The details of the pharmacist’s authority are left up to the protocol (subject to approval by the Board) and the statute and rules have been interpreted not to require an established

335. WASH. REV. CODE ANN. § 18.64.011(10)-(11) (West, WESTLAW through 1999) (emphasis added). In 1979, the Pharmacy Practice Act was revised to read as it does presently, the revision included the phrase cited above as part of the definition of the practice of pharmacy that enables prescription power (“initiation of drug therapy” as defined by administrative rule) with collaboration (in accordance with written guidelines or protocols).

336. WASH. ADMIN. CODE § 246-863-100 (West, WESTLAW through Jan. 5, 2000).

337. *Id.*

338. *Id.*

339. *Id.*

340. Telephone Interview with Georgia Robinson-Sage, Administrative Assistant, Washington State Board of Pharmacy (Jan. 18, 2000).

341. Telephone Interview with Tim Fuller, Pharmacy Consultant, Washington State Board of Pharmacy (Jan. 18, 2000).

or ongoing relationship of the patients with the collaborating doctor (unless the protocol so requires).³⁴²

Since the Washington Pilot Project ended in 1997, an increasing number of pharmacists have started to and continued to exercise dependent prescribing power for ECPs.³⁴³ There are currently over 415 protocols on file in Washington, and about 150 of those involve ECPs.³⁴⁴

b) *Characteristics of the Washington Model that Make it the Paradigm for States Wishing to Increase Access to ECPs Through Dependent Pharmacist Prescribing*

Five key characteristics that distinguish the Washington model of dependent pharmacist prescriptive power from collaborative drug therapy management in other states make this model ideal for increasing access to ECPs.

First, the prescriptive authority is not restricted to pharmacists practicing in institutional settings like hospitals, HMOs, or nursing homes. Restricting expanded pharmacist practice to institutions is in part in order to make sure that the pharmacist has access to the patient's medical records.³⁴⁵ However, for ECP prescribing access to medical records is not necessary because patients can easily be screened with a few simple inquiries.³⁴⁶ Additionally, for the dependent pharmacist prescriber proposal to have much impact on increasing access to ECPs, women must be able to obtain ECPs from their retail pharmacist, since the retail pharmacists are the ones who are more likely to be within close geographic proximity and who can provide the extended-hour services that are quick and not intimidating. Furthermore, women can already go to a hospital emergency room to try to get ECPs; thus, allowing only hospital pharmacists to dependently prescribe does not increase access and would not further this proposal's purpose of making ECPs more accessible to women in a timely, convenient, and discrete setting.

Second, there are no educational requirements for the pharmacists other than basic licensure and any training prescribed by

342. *Id.*

343. *Id.*

344. *Id.*

345. See ACCP Position Statement, *supra* note 70, at 328 (supporting collaborative practice in institutional environments so that the pharmacists can have access to the patient's medical records).

346. See *supra* Part III.B.5.c. (discussing screening mechanisms).

the protocol. The absence of state mandated certification/additional degree requirements means that a greater number of pharmacists are likely to be able to participate in the dependent pharmacist prescribing of ECPs, and where there are fewer obstacles to pharmacist participation, there is a better chance for greater access. Certainly, it is vital that the pharmacists be knowledgeable about the product they are prescribing and the condition for which they are prescribing, but the collaborating physician and pharmacist are in the best positions to determine whether additional education is required; furthermore, pharmacists are likely to have sufficient information because the protocols must be specific enough to guide the pharmacist and ensure that the pharmacist has sufficient information with which to make prescribing determinations.

Third, the patient for whom the pharmacist is prescribing need not have a prior or ongoing relationship with the collaborating physician.³⁴⁷ As long as the patient consults with the dependent pharmacist prescriber, the pharmacist, using the protocol but without concurrent involvement by the collaborating doctor, will be able to determine whether an ECP prescription would be safe and appropriate for the woman, and thus the pharmacist will be able to write a valid prescription under federal case law.³⁴⁸ Since patient safety is protected through the good safety profile of ECPs and through the screening mechanism, a requirement that the patient have an ongoing and established relationship with the collaborating physician merely serves to limit the availability of the ECPs without a real safety purpose. By only enabling women to obtain ECP prescriptions from a pharmacist with whom her doctor had a protocol, women (particularly socio-economically disadvantaged ones) are effectively disempowered if they do not have an ongoing doctor-patient relationship with any provider, if they do not know with which pharmacist their doctor has a protocol,³⁴⁹ and if they, for

347. This Washington model characteristic is shared only by New Mexico. All other states with any type of collaborative drug therapy management power require that the patient have an established and ongoing relationship with the collaborating doctor. See *infra* Part IV.B.2-3.

348. See *supra* Part III.D.2. (explaining why the lack of a relationship between the patient and the collaborating physician does not result in the invalidation of an ECP prescription written by a dependent pharmacist prescriber).

349. In order to take advantage of the pharmacist prescribing, the woman would have to contact her doctor to find out which pharmacists she could see; the imposition of such a requirement defeats the purpose of pharmacist prescribing, which enables women to avoid the process of contacting their doctor for a prescription. If a

whatever reason, are very far away from any pharmacist with whom their doctor has a protocol. Additionally, such a requirement imposes greater transaction costs on pharmacists, because they must make sure that the woman requesting the ECPs is an ongoing patient of the pharmacist's collaborating physician, and because the pharmacist may feel the need to make protocols with a variety of doctors in order to actually be able to serve a significant portion of the women living in close proximity to the pharmacy.³⁵⁰ An ongoing doctor-patient relationship for dependent pharmacist prescribing may be important for situations where the pharmacist is monitoring a drug therapy regime for a disease diagnosed by the physician, since doctor involvement is necessary for ongoing problems that require continual diagnostic reevaluation;³⁵¹ however, the need for ECPs is an isolated problem that does not require a traditional doctor's diagnosis, and thus limiting ECP prescriptions by pharmacists to women with an ongoing relationship with the collaborating physician merely serves to impose greater costs and barriers, thereby defeating much of the purpose of the dependent pharmacist prescriber proposal designed to minimize costs and increase access to ECPs.³⁵²

Fourth, the Washington model does not require that the protocols be patient-specific.³⁵³ While some state pharmacist collaborative programs require that the protocols be patient-specific (and not merely restricted to patients with relationships with the collaborating doctor), this restriction to the dependent pharmacist prescribing power would make this paper's proposal worth-

woman had to contact her doctor to find out which pharmacists she could see for a prescription, she could just as easily get the doctor to call the doctor's own prescription into a local pharmacy.

350. So too might a physician feel compelled to make protocols with a wide variety of pharmacists in order to provide options for the physician's patients who are likely to live in a dispersed area, thereby further increasing transaction costs.

351. See ACCP Position Statement, *supra* note 70, at 328.

352. See *supra* Part III.B.1-2. (discussing these factors as motivating the proposal for dependent pharmacist prescribing of ECPs).

353. This can be seen as a subpoint to the third characteristic of the requirement of a doctor patient relationship, but it will be treated separately for the purposes of this paper 1) because it has separate implications for the ability of state laws to accomplish the goals of the pharmacist prescriber proposal for ECPs, and 2) because some states require patient specificity, and not just an ongoing doctor-patient relationship. All states requiring patient-specific protocols necessarily require an ongoing doctor-patient relationship, so other states will be described as not having the doctor-patient relationship requirement, having a doctor-patient relationship requirement (but not a patient-specific protocol requirement), or requiring a patient-specific protocol (which necessarily also requires an ongoing doctor-patient relationship).

less unless doctors developed a protocol with a pharmacist for every individual patient of the doctor, which would certainly entail an inefficient amount of time and expense.

Fifth, the scope of pharmacist authority in the Washington model enables pharmacists to *initiate* drug treatment when there is no prior or ongoing drug therapy or no previous doctor-diagnosed medical condition. It is this broad authority that enables pharmacists to prescribe ECPs for women; in many other states pharmacist power is restricted to monitoring, modifying, or continuing drug therapy or managing a particular ongoing disease, but the pharmacist may not prescribe something that is unrelated to the management of an ongoing doctor-diagnosed problem (this limit necessarily ties into the third characteristic of the doctor-patient relationship requirement). Since the need for ECPs is an isolated event, unrelated to ongoing treatments or particular diseases, ECPs could not be the subject of protocols in many states. For dependent pharmacist prescribing to have the impact of increasing access, the pharmacists must have the power to evaluate/diagnose the patient's problem without involvement by the physician and must have the power to initiate/write their own prescription for ECPs.

All other states with de jure collaboration between pharmacist and physicians vary around these five major characteristics, in the restrictions on the authority granted to pharmacists, and are thus less than ideal in some way. However, there is a tremendous amount of potential for increased access to ECPs based on the existing state models of collaborative practice, and the remainder of this section attempts to explain the authority in various states, to highlight the advantages and disadvantages of the systems in relation to this paper's proposal of increasing ECP access, and to discuss the states' (largely politically driven) prospects for moving toward the Washington model.

2. Florida: State Where Pharmacists Have Limited Independent Prescribing Authority, but Lack Washington Model Dependent Pharmacist Prescribing Power

Florida pharmacists can exercise independent prescriptive authority for drugs listed on an administratively adopted formu-

lary.³⁵⁴ Independent prescriptive authority means that a pharmacist can order a drug for a patient without the patient ever seeing a doctor and without any type of collaborative agreement between the pharmacist and any physician. However, the only drugs on the formulary for independent prescribing are those that fall into one of the seven legislatively enacted categories of drugs.³⁵⁵ Because ECPs do not fall into one of those categories, the ECPs cannot be administratively added to the formulary for independent prescribing without legislative action; such legislative action would have to either create another formulary category that could include ECPs or such action would have to list ECPs in the statute explicitly.³⁵⁶ John Taylor, Executive Director of the Florida State Board of Pharmacy, indicated that he is not aware of any discussion to make such a legislative change that would enable independent pharmacist prescribing of ECPs.³⁵⁷

Although Florida pharmacists can independently prescribe formulary drugs, they are not authorized to engage in collaborative practice with physicians whereby the pharmacist and physician would create a protocol for initiation, modification, and/or management of drug therapy for patients involving drugs not on the formulary.³⁵⁸ However, there has been discussion in Florida about expanding the pharmacist's role to include drug therapy management that would enable pharmacists to alter drug dosages or to change drugs for an ongoing therapy in accordance with an established protocol.³⁵⁹ This discussion does not include formal prescribing or "initiation" by the pharmacists in accordance with the protocol; the model currently envisioned allows for modification/monitoring/continuing and merely creates a standing medical order that the pharmacist exercises after an examination and

354. The "practice of pharmacy" includes "dispensing . . . pursuant to prescriptions[.]" and a "prescription" includes "a pharmacist's order for a product selected from the formulary created pursuant to § 465.186." FLA. STAT. ANN. § 465.003 (13), (14) (West, WESTLAW through 1999). Thus, pharmacists can prescribe and dispense to patients/customers drugs from the formulary created pursuant to § 465.186. Together, the Boards of Pharmacy, of Medicine, and of Osteopathic Medicine are authorized to adopt a formulary for independent prescription of drugs in the drug categories established by the legislature. See FLA. STAT. ANN. § 465.186(2) (West Supp., WESTLAW through 1999).

355. See FLA. STAT. ANN. § 465.186(1) (West, WESTLAW through 1999) (listing the categories).

356. Telephone Interview with John D. Taylor, Executive Director, Florida State Board of Pharmacy (Jan. 18, 2000).

357. *Id.*

358. *Id.*

359. *Id.*

diagnosis by the collaborating physician.³⁶⁰ Thus, even if such collaborative practice was enacted in Florida, the Washington model dependent pharmacist prescribing of ECPs would not fall within authorized collaborative practice as currently envisioned in Florida.

3. States Where Pharmacists Have Varying Degrees of Expanded Practice Authority, Available Based on Collaborative Protocols, but Lack Sufficient Legal Authority for Washington Model Dependent Pharmacist Prescribing

The following are states where pharmacists' roles have been expanded beyond mere dispensing to include some type of collaboration with practitioners, but where pharmacists cannot actually issue prescriptions themselves.³⁶¹ All of these states require patients of collaborating pharmacists to have an ongoing doctor-patient relationship with the collaborating physician; this characteristic of collaborative practice in the majority of states is one of the key barriers to the expansive access enabled by the Washington model of dependent pharmacist prescribing of ECPs. As to the remaining major characteristics of the collaborative practices, states that allow broad power in one area tend to have narrow restrictions in other areas in order to rein in the breadth of collaborative practice.

a) *Mississippi and South Dakota: Examples of States Where Collaborative Practice Is not Restricted to Institutions*³⁶²

(1) *Mississippi*

Mississippi Code § 73-21-73 defines the "practice of pharmacy" to include "initiating or modifying of drug therapy in accordance with written guidelines or protocols previously

360. *Id.*

361. In Washington and New Mexico, when a prescribing pharmacist or pharmacist clinician issues a prescription, it is the pharmacist who signs and authorizes the dispensation of the medication, whereas, in many of the states in this section, even where a pharmacist can modify drug dosage and therapy, the practitioner's name is still the ultimate authority on the prescription, and it is the practitioner's name, not the pharmacist's name, that goes on the prescription. Recall the differences between drug therapy management and dependent pharmacist prescribing as discussed, *supra*, in Part IV.A.2.

362. Other states where collaborative practice is not restricted to institutions include Arkansas, Idaho, Kentucky, Minnesota, Nebraska, Ohio, Oregon, Texas, and Virginia. See *infra* Appendix A.

established and approved by the board” and defines “written guideline or protocol” to be “an agreement in which any practitioner authorized to prescribe drugs delegates to a pharmacist authority to conduct specific prescribing functions in an institutional setting, or with individual patients, provided that a specific protocol agreement is signed on each patient and is filed [with the board].”³⁶³

Mississippi drug therapy management, more appropriately termed “disease state management,” imposes additional education/training requirements on prescribing pharmacists; in order to initiate or modify drug therapy in accordance with a protocol, a pharmacist must be state certified in management of a particular disease state, such as diabetes.³⁶⁴ Certification requires completion of Board approved study courses on each disease state in which the pharmacist wishes to be certified; certification may be renewed every two years if the pharmacist completes additional continuing education.³⁶⁵ Pharmacists can only participate in initiation/modification of drug therapies for patients involving the particular disease state for which they are certified.³⁶⁶

Mississippi disease state management allows for pharmacists to initiate prescriptions in accordance with a protocol. However, the regulations differentiate between institutional and outpatient pharmacists; the pharmacists in an out-patient setting can only initiate or modify drug therapy based on patient-specific protocols, where the institutional pharmacists can initiate or modify based on the written protocol, which need not be patient-specific.³⁶⁷

Since outpatient pharmacists can only initiate drug therapy based on patient-specific protocols, and because ECPs do not fall into a category of disease states for which a pharmacist can be certified, Mississippi pharmacists are not currently positioned to exercise dependent pharmacist prescribing for ECPs. Furthermore, it is unlikely that outpatient pharmacists will be able to initiate drug treatments on non patient-specific protocol basis.³⁶⁸

363. MISS. CODE ANN. § 73-21-73(aa), (jj) (LEXIS through 1999).

364. MISS. REG. 50-018-001(2)(C) (LEXIS through 1999).

365. *Id.*

366. *Id.*

367. *Id.* at 50-018-001(1).

368. Telephone Interview with Harrold Stamps, Director of Compliance, Mississippi State Board of Pharmacy (Jan. 13, 2000).

(2) *South Dakota*

According to South Dakota Codified Laws § 36-11-19.1, a registered pharmacist may “[i]nitate or modify drug therapy by protocol or other legal authority established and approved within a licensed health care facility or by a practitioner authorized to prescribe drugs.”³⁶⁹ Although this section allows for both institutional and outpatient collaborative drug therapy, the role within institutions is of more significance because institutional collaborative pharmacist drug therapy is much more common.³⁷⁰ Although the drug therapy management authorized by statute includes “initiat[ion],” such authority does not allow for the pharmacist to prescribe; in fact, South Dakota Codified Laws § 36-11-2.2, defining the “practice of pharmacy,” explicitly states that “[t]he practice of pharmacy does not authorize a pharmacist to prescribe drugs as a practitioner.”³⁷¹

Although the South Dakota model is part of the way to the Washington model, in that outpatient pharmacists can participate in collaboration without additional training on a general, rather than patient-specific protocol basis, there have been no real requests for South Dakota to adopt the Washington model, although it might happen “down the road.”³⁷² The real focus of the collaboration is on physicians and pharmacists working together more closely to select the best drug.³⁷³ Additionally, South Dakota may not have a politically favorable climate to increasing access to ECPs, as it is a relatively conservative state. According to Dennis Jones, Executive Secretary of the South Dakota State Board of Pharmacy, pharmacists in South Dakota have supported the conscience clause legislation that has been passed and, rather than pushing for increased access to ECPs, the pharmacists are more likely to be concerned about not providing ECPs if they morally or religiously object.³⁷⁴

369. S.D. CODIFIED LAWS §36-11-19.1 (LEXIS through 1999).

370. Telephone Interview with Dennis M. Jones, Executive Secretary, South Dakota State Board of Pharmacy (Jan. 14, 2000).

371. S.D. CODIFIED LAWS §36-11-2.2 (LEXIS through 1999).

372. Telephone Interview with Dennis M. Jones, Executive Secretary, South Dakota State Board of Pharmacy (Jan. 14, 2000).

373. *Id.*

374. *Id.*

b) *California and North Dakota: Examples of States Where Collaborative Practice Is Restricted to Institutional Settings*³⁷⁵

(1) *California*

According to California Business and Professions Code § 4052(a)(4) and (a)(5)(A), California pharmacists practicing in institutional facilities can engage in drug therapy management pursuant to protocols.³⁷⁶ Section 4052(a)(4) deals with practice only in a licensed health care facility, while § 4052(a)(5)(A) deals with collaborative practice in broader institutional settings, including a home health agency, a clinic with physician oversight, and where a provider contracts with licensed health care service plans.³⁷⁷

Under § 4052(a)(4), pharmacists in licensed health care facilities can “initiat[e] or adjust[] the drug regimen of a patient pursuant to an order or authorization made by the patient’s prescriber and in accordance with the policies, procedures, or protocols of the licensed health care facility.”³⁷⁸ In this setting, the protocols may be general, rather than patient-specific because there is clear physician oversight.³⁷⁹

In contrast, protocols for pharmacist drug therapy management must be patient-specific when collaborative practice is exercised in broader settings.³⁸⁰ Additionally, in the broader institutional practice setting the pharmacist must, at a minimum, have access to the patient’s medical records, and the pharmacist’s actions can only “relate to a condition for which the patient has first been seen by a physician.”³⁸¹

While, the pharmacist can “initiate or adjust[]” drug therapy in the narrow institutional settings under § 4052(a)(4)(D), and while a pharmacist in a broader institutional setting is restricted only to “adjusting” drug therapy pursuant to § 4052(a)(5)(iv), all de jure collaborative practice by pharmacists is restricted to some type of institutional setting.³⁸² As to addi-

375. Other states where collaborative practice is restricted to institutional settings include Indiana, Kansas, Nevada, and Vermont. *See infra* Appendix A.

376. CAL. BUS. & PROF. CODE § 4052(a)(4), (a)(5)(A) (LEXIS through 1998).

377. *Id.*

378. *Id.* at § 4052(a)(4)(D).

379. *Id.*; 1999 Cal. Adv. Legis. Serv. 375 (LEXIS) (adding § 4052(a)(5)(C)(iv)).

380. CAL. BUS. & PROF. CODE § 4052(a)(5)(A)(iv) (LEXIS through 1998).

381. 1999 Cal. Adv. Legis. Serv. 375 (LEXIS) (adding § 4052(a)(5)(C)(ii), (iii)).

382. CAL. BUS. & PROF. CODE § 4052(a)(4), (a)(5) (LEXIS through 1998).

tional education and training required for the exercise of collaborative practice in the narrow institutional setting, a pharmacist must be trained/familiarized with the health care facility's policies, procedures, and protocols, and if exercising collaborative practice in the broader institutional setting, a pharmacist must either have "(1) successfully completed clinical residency training; or (2) demonstrated clinical experience in direct patient care delivery."³⁸³

While these types of collaborative practices are very common in HMOs and county hospitals,³⁸⁴ they do not allow for dependent pharmacist prescribing according to protocols in outpatient settings, as would be required to implement the Washington model dependent pharmacists prescribers of ECPs. If collaborative practice is extended to pharmacists practicing in outpatient settings, it would still likely be restricted to adjusting doses and drugs in accordance with protocols, and not prescribing.³⁸⁵ Pharmacist authority in California is unlikely, in the near future, to expand to include outpatient pharmacist initiation/prescription under protocols that would enable pharmacists to dependently prescribe like their counterparts in Washington, although it is unclear what might happen farther in the future.³⁸⁶

(2) *North Dakota*

Pharmacists in North Dakota have limited prescriptive privileges under North Dakota Century Code § 43-15-31.4, which provides that "[a] licensed pharmacist in an institutional setting has limited prescriptive practices to initiate or modify drug therapy following diagnosis and initial patient assessment by a licensed physician, under the supervision of the same licensed physician"³⁸⁷ The scope of the pharmacist's prescriptive practice is set by the collaborative agreement prepared by the physician and pharmacist; the collaborative agreement must be filed with and approved by a prescriptive committee with representatives from both the Board of Pharmacy and the Board of Medical Examiners.³⁸⁸

383. *Id.* at § 4052(b).

384. Telephone Interview with Dolly Harris, Inspector, California State Board of Pharmacy (Jan. 13, 2000).

385. *Id.*

386. *Id.*

387. N.D. CENT. CODE § 43-15-31.4(1) (West, WESTLAW through 1999).

388. *Id.* at § 43-15-31.4(2), (4).

Although collaborative practice in North Dakota is limited to pharmacists practicing in institutional facilities, it is general to the doctor and pharmacist, rather than patient-specific. Additionally, the inclusion of "initiation" power for pharmacists evidences broad power, although it is not quite "prescriptive" since it must follow a doctor's diagnosis. This growing authority for pharmacists is evidenced by North Dakota Senate Bill number 2176, enacted March 5, 1999, which changed the definition of practitioner in § 43-15-01 from explicitly excluding pharmacists to including any "individual licensed, registered or otherwise authorized by the jurisdiction in which the individual is practicing to prescribe drugs in the course of professional practice."³⁸⁹

While the law has expanded pharmacists' authority, pharmacists and physicians have not fully taken advantage of the existing law, in part due to the Board of Medical Examiner's reluctance to approve expansive protocols.³⁹⁰ As a result, there is a general lack of interest in expanding the role of the pharmacist even further toward a Washington-like model.³⁹¹ In addition, Howard Anderson, the Executive Director of the North Dakota State Board of Pharmacy, indicated that expanding access to ECPs may be politically unpopular, both with the legislature and with some pharmacists who are concerned about conscience clause issues.³⁹² Although there was some discussion about ECPs in North Dakota, most women in need of ECPs do not have trouble seeing/contacting their doctor and could get ECPs within an hour of need; consequently, the North Dakota medical and pharmacy communities are not likely to want to change their current law to accommodate something that is not perceived to be a problem.³⁹³

389. S.B. 2176, 56th Leg. (N.D. 1999) (enacted). The previous language defined "practitioner" to be "a physician, dentist, veterinarian, scientific investigator, or other person (other than pharmacists) licensed by North Dakota and permitted by such license to dispense, conduct research with respect to or administer drugs in the course of professional practice or research in North Dakota." N.D. CENT. CODE § 43-15-01(24) (1997) (no longer in force).

390. Telephone Interview with Howard C. Anderson, Jr., Executive Director, North Dakota State Board of Pharmacy (Jan. 14, 2000).

391. *Id.* Collaborative practice in North Dakota currently does not allow Washington-like dependent pharmacist prescribing of ECPs primarily because of the requirements that the pharmacist must be practicing within an institution and that there must be an ongoing doctor patient relationship.

392. *Id.*

393. *Id.*

4. Iowa and Maine: Examples of States Where Pharmacists Have No Collaborative Practice Authority³⁹⁴

While a number of states do not have any type of de jure collaborative practice under which pharmacists can initiate or modify drug treatment, the vast majority have at least discussed the issue in some form. An understanding of the status of these states helps to provide a more complete view of how the role of pharmacists is expanding, of the debate and controversy surrounding such expansion, and of the likelihood that such discussions will lead to an increase in the number of states where ECPs may be accessible through dependent pharmacist prescribers.

a) *Iowa*

While the Iowa Code definition of the "practice of pharmacy" as "a dynamic patient-oriented health service profession that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use and related drug therapy"³⁹⁵ seems to suggest that Iowa pharmacists could participate in some type of collaborative drug therapy, such authority is the subject of great controversy.³⁹⁶

Five years ago, the Board of Pharmacy tried to promulgate an administrative rule allowing collaborative drug therapy, but it was opposed by the medical and pharmaceutical communities.³⁹⁷ Then the Board adopted guidelines for collaborative agreements, but organized medicine objected, so the guidelines were withdrawn.³⁹⁸ Recently, the Board tried to propose a rule to allow pharmacists to perform immunizations under collaborative agreements, but the medical opposition to such a move resulted in this authority being limited to cover only two vaccines.³⁹⁹ The medical community seems to want a very narrow role for Iowa pharmacists which may be, in part, a backlash to the numerous changes in Iowa allowing physician assistants and nurse practitioners significant breadth in their practices.⁴⁰⁰

394. Other states where pharmacists have no collaborative practice authority include Arizona, Massachusetts, and New York. See *infra* Appendix A.

395. IOWA CODE § 155A.3(27) (LEXIS through 1997).

396. Telephone Interview with Lloyd K. Jessen, Executive Director, Iowa State Board of Pharmacy (Jan. 14, 2000).

397. *Id.*

398. *Id.*

399. *Id.*

400. *Id.*

The heated controversy surrounding collaborative practice is unlikely to be solved either by agency rulemaking (which has already failed after repeated attempts) or by an opinion by the attorney general (who is reluctant to give an opinion that interprets the definition of pharmacy to include the ability to exercise collaborative drug therapy under protocols).⁴⁰¹ Resolution will likely have to come from the legislature, and potential proposals are currently being drafted on both sides of the issue.⁴⁰² Additionally, the governor is relatively new; so although the governor spoke in favor of the concept of collaborative practice last year, it is difficult to know where he stands on this controversial topic.⁴⁰³

Clearly there is no current authority for dependent pharmacist prescribing of ECPs; Iowa will have to wait to see if and when the collaborative practice issue is resolved by the legislature.

b) *Maine*

Although Maine recently redefined “practitioner” so that it no longer explicitly excludes pharmacists,⁴⁰⁴ pharmacists in Maine do not have any prescriptive or collaborative drug therapy management authority.

In the same bill that redefined “practitioner,” the Maine legislature established a Pharmacy Act Review Committee, to study among other things, the potential expansion of the pharmacist’s scope of practice.⁴⁰⁵ The Report of the Pharmacy Act Review Committee to the Governor and the Joint Standing Committee on Business and Economic Development on Pharmacy Scope of Practice found that while pharmacy has historically been a prod-

401. *Id.*

402. *Id.*

403. *Id.*

404. 1999 Me. Laws 130 at § 4 (amending ME. REV. STAT. ANN. tit. 34, §13702(23) to define “practitioner” as “an individual who is licensed, registered or otherwise authorized in the appropriate jurisdiction to prescribe and administer drugs in the course of professional practice[.]” thereby replacing the previous definition of “practitioner” which was “a physician, dentist, podiatrist, veterinarian, scientific investigator or other person, other than pharmacists, licensed in the United States and Canada to dispense, conduct research with respect to or administer drugs in the course of professional practice or research”).

405. *Id.* at pmb1. The Review Committee in Maine is just one of many study groups that have been established in states around the country regarding expanding the scope of the practice of pharmacy. The existence of a final report from the Committee makes it relevant to discuss as the report indicates another one of many differing perspectives on the issue of expanded practice.

uct-based rather than a service-based field, a number of states have expanded the scope of pharmaceutical practice into more service-oriented areas through collaborative drug therapy management or disease state management.⁴⁰⁶ While the Committee expressed concern about pharmacy graduates not wanting to practice in Maine because of more attractive practice options that involve greater responsibility elsewhere, the Committee felt that it was without sufficient information to assess the costs and benefits of expanded practice.⁴⁰⁷ Therefore the Committee declined to make a recommendation to the Board or to the Legislature about expanding pharmacy practice, primarily because of the lack of experience and lack of studies regarding actual collaborative practice in both Maine and nationally.⁴⁰⁸ The Committee did recommend that the issue be studied further by another Committee with a narrower and more directed scope for study, with sufficient time, with appropriate funding, with more public comment/involvement, and perhaps with isolated collaborative care pilot studies in Maine.⁴⁰⁹ However, the Chair of the Committee, Ms. Anne Head, dissented from the recommendation supporting the reauthorization of a study committee, concluding that perhaps "the issue is not ripe for meaningful change [and that] it would be preferable for the profession and interested parties to shoulder the burden of developing legislation."⁴¹⁰

It is unclear as to what will be done with the findings and recommendations of the Committee. Until the pharmacist's role in Maine is expanded significantly beyond its current scope, women in Maine will not be able to obtain ECPs from Washington model dependent pharmacist prescribers.

V. CONCLUSION

Although collaborative practice is relatively new and somewhat restricted in many states, the nationwide trend toward the expansion of the role of the pharmacist is a promising step toward Washington model dependent pharmacist prescribing of

406. DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION, REPORT OF THE PHARMACY ACT REVIEW COMMITTEE TO THE GOVERNOR AND THE JOINT STANDING COMMITTEE ON BUSINESS AND ECONOMIC DEVELOPMENT ON PHARMACY SCOPE OF PRACTICE 9-10 (Dec. 22, 1999) (available at <<http://www.state.me.us/pfr/led/pharmacy/index.htm>>).

407. *Id.* at 12-13.

408. *Id.*

409. *Id.* at 13-15.

410. *Id.* at 16.

ECPs. Dependent pharmacist prescribing can dramatically increase access to ECPs if the pharmacy and medical communities agree to work together. This collaboration and delegation of prescriptive authority is both justified and necessary, especially in the context of ECPs — justified, in that women's safety will still be protected since the prescription of ECPs does not require a physical exam or complex diagnosis nor do ECPs pose a significant health risk; necessary, in that without increased access, many women are effectively deprived of this additional chance to control their reproductive futures and, without increased access, we waste a valuable tool in society's efforts to reduce unintended pregnancies, abortions, and the detrimental health and economic consequences that thereby result.

Until a nationwide solution to the problem of ECP access is available, private initiatives to increase access and education should be continued, and states should be lobbied to relax their current laws/regulations or to create new laws/regulations that allow pharmacists and physicians to collaborate to provide easier ECP access as part of an effort to increase the quality of reproductive health care available to women. As more states allow for dependent pharmacist prescribing of ECPs, Washington, New Mexico, and other states will lead the way toward greater acceptance of both collaborative pharmacy practice as an efficient method of filling gaps in the provision of health care, and of ECPs as a safe, effective, and much needed method of contraception.

APPENDIX A

Factors → States ↓	Status of De Jure Collaborative Practice	Settings for the Expanded Pharmacist Practice	Additional Pharmacist Training Required by Statute or Reg. ⁶	Ongoing Patient Relationship w/ Collaborating Doctor	Patient or Disease Specific Protocols	Scope of Authority	Is dependent pharmacist prescribing of ECPs likely soon?
Ariz.	NO ARIZ. REV. STAT. § 32-1901 (LEXIS through 1999). However, a bill may be introduced for CDTM this year. Telephone interview with Lynn Lloyd, Executive Director, Arizona State Board of Pharmacy (Jan. 13, 2000).	Potential bill would likely restrict to institutions.		Doctor		Bill would likely include some modification but no initiation or WA-model dependent prescribing.	UNLIKELY. While the details of a potential bill proposal remain unclear, it is unlikely that Arizona's next step in expanding the role of pharmacists will enable Washington-like dependent pharmacist prescribers of ECPs. <i>Id.</i>
Ark.	YES -- two types (DSM & CDTM). H.B. 1066, 82d Gen. Ass. (Ark. 1999) (enacted) (modifying the definitions of "practice of pharmacy" and "pharmacy care" in Ark. Code Ann. § 17-92-101(14)(A), (15) to include disease state management in addition to the previously existing CDTM).	DSM: ALL CDTM: ALL	DSM: YES disease state credentialing.	DSM: YES	DSM: DISEASE & PATIENT	DSM: disease state management under written protocol (includes initiation/prescription for the disease state). CDTM: monitor, continue drug therapy, but not WA-model dependent prescribing.	UNLIKELY: Attempts to provide easier access to ECPs would likely face significant political opposition. Interview with Charlie Campbell, Executive Director, Arkansas State Board of Pharmacy (Jan. 18, 2000).
Cal.	YES CAL. BUS. & PROF. CODE § 40526(c), (d), (e), (f) (LEXIS through 1998); 1999 CAL. ADV. LEGIS. SERV. 375 (LEXIS) (adding § 40526)(S)(C)(d), (f)(b), (f)(v)). NO, but some discussion.	INSTITUTIONS: where there is access to medical records.	VARIES: based on the type of setting.	YES	VARIES: patient in some settings; neither in others.	CDTM: monitor/modify in some settings; initiate/monitor/modify in others, but no WA-model dependent prescribing.	UNCLEAR: <i>see supra</i> Part IV, B.3.b.1.
Fla.	NO, but some discussion. FLA. STAT. ANN. § 465.003(12), (13) (West, WESTLAW through 1999).					Pharmacists have independent prescribing of formulary drugs, but no expanded collaborative practice authority.	UNLIKELY: <i>see supra</i> Part IV, B.2.
Idaho	YES IDAHO ADMIN. CODE § 27.01.01.165 (West, WESTLAW through 1999) (authorizing CDTM, termed "pharmacotherapy"); IDAHO CODE § 34-1704, (LEXIS through 1999) (defining "practice of pharmacy" to include "provision of those acts or services necessary to provide pharmaceutical care").	ALL	NO	YES	NEITHER	CDTM for drug or disease therapy management, including (after physician diagnosis) implementation, monitoring, modifying, but not WA-model dependent prescribing. IDAHO ADMIN. CODE § 27.01.01.165(01)(b)-(c); .65(02)(b)(ii) (West, WESTLAW through 1999).	NOT YET DISCUSSED: Since the administrative rule is so new, Idaho will likely wait and see how the collaborative practices work before taking any further action; plans for expanding the role of pharmacists to a Washington-like model under which pharmacists could prescribe ECPs have not been discussed. Telephone interview with Richard "Mick" Markuson, Executive Director of the Idaho State Board of Pharmacy (Jan. 18, 2000).

Factors ↑ States ↓	Status of De Jure Collaborative Practice	Settings for the Expanded Pharmacist Practice	Additional Pharmacist Training Required by Statute or Reg. ^a	Ongoing Patient Relationship w/ Collaborating Doctor	Patient or Disease Specific Protocols	Scope of Authority	Is dependent pharmacist prescribing of ECPs likely soon?
Iad.	YES IND. CODE ANN. § 25-26-16-1 to -9 (LEXIS through 1999).	INSTITUTIONS: need medical record access.	NO	YES	NEITHER	CDTM including monitoring and modification but not WA-model dependent prescribing.	UNCLEAR
Iowa	NO, but a matter of debate. IOWA CODE § 155A.3(27) (LEXIS through 1997).	INSTITUTIONS: need medical record access.	--	YES	NO	CDTM including monitoring and modification (supervising physician must "sign off" on the changes made under the protocol. No WA-model dependent prescribing.	UNLIKELY: Because of historical controversy, implementation of collaborative practice will have to come from the legislature. Telephone interview with Lloyd K. Jessen, Executive Director, Iowa State Board of Pharmacy (Jan. 14, 2000).
Kan.	YES KAN. STAT. ANN. §65-2872 (LEXIS through 1999). Op. Kan. Att'y Gen. 81-182 (1981) (discussing, in part, a physician's authority to delegate under the statute, and interpreting the statute to mean that pharmacists acting pursuant to a physician's protocol are not acting outside the scope of their authorized practice).	INSTITUTIONS: need medical record access.	NO	YES	PATIENT	CDTM: can create "collaborative care agreements" including modifying and monitoring after doctor diagnosis, but not WA-model dependent prescribing.	UNLIKELY: While there is a trend in Kansas away from product-oriented pharmacy practice to service-oriented pharmacy practice, expanding collaborative practice to retail pharmacies is problematic because of the lack of access to medical records; current discussion of possible expansion of pharmacist roles focuses on developing disease state management modeled after Mississippi. Telephone interview with Chris Gassen, Inspector, Kansas State Board of Pharmacy (Jan. 14, 2000).
Ky.	YES KY. REV. STAT. ANN § 315.010 (LEXIS through 1998) (allowing pharmacists to enter into "collaborative care agreements").	ALL	NO	YES	PATIENT	CDTM: can create "collaborative care agreements" including modifying and monitoring after doctor diagnosis, but not WA-model dependent prescribing.	UNLIKELY: The Kentucky Board of Pharmacy does not have a real sense of how common collaborative agreements are or how receptive physicians and pharmacists have been to this practice; Kentucky collaborative practice is unlikely to be expanded to WA-model any time soon. Telephone interview with Jeff Osman, Pharmacy Inspections & Investigating Coordinator, Kentucky State Board of Pharmacy (Jan. 14, 2000).
Me.	NO But see 1999 Me. Laws 130 at §4 (changing the definition of "practitioner" in ME. REV. STAT. ANN. tit. 34, §1370(23), so as not to specifically exclude pharmacists).						UNCLEAR: A Maine committee recently studied and reported on the possibility of expanding the role of pharmacists. DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION, REPORT OF THE PHARMACY ACT REVIEW COMMITTEE TO THE GOVERNOR AND THE JOINT STANDING COMMITTEE ON BUSINESS AND ECONOMIC DEVELOPMENT ON PHARMACY SCOPE OF PRACTICE 9-10 (Dec. 22, 1999) (available from <http://www.state.me.us/pfr/inf/inf/pharmacy/index.htm>). It is unclear what changes will result from this study.

Factors → States ↓	Status of De Jure Collaborative Practice	Settings for the Expanded Pharmacist Practice	Additional Pharmacist Training Required by Statute or Reg. ⁶	Ongoing Patient Relationship w/ Collaborating Doctor	Patient or Disease Specific Protocols	Scope of Authority	Is dependent pharmacist prescribing of ECPs likely soon?
Mass.	NO, but CDTM bill may be proposed next year.						PERHAPS, but it is premature to speculate. Before pursuing any type of expanded role for pharmacists, Massachusetts wants to standardize pharmacist technician qualifications; next year, legislation may be introduced expanding the pharmacist role into CDTM allowed pursuant to very strict protocols. Telephone Interview with Charles Young, Executive Director, Massachusetts State Board of Pharmacy (Jan. 14, 2000).
Minn.	YES MINN. STAT. § 151.01(27) (LEXIS through 1999) (defining "practice of pharmacy"); MINN. R. 6800.0100 (LEXIS through 1998) (defining "pharmaceutical care").	ALL	NO	YES	PATIENT	CDTM for drug therapy/disease management, including monitoring and modifying, but not WA-model dependent prescribing.	UNLIKELY: Minnesota is unlikely to expand pharmacist authority to include formal prescription; with less than 12 pharmacists currently involved in collaborative protocols, Minnesota legislative and administrative officials want to wait to see how well this collaborative practice works before making further changes. Telephone Interview with David E. Holmsroun, Executive Director, Minnesota State Board of Pharmacy (Jan. 13, 2000).
Miss.	YES (differentiates based on setting) MISS. CODE ANN. §73-21-73(aa), (j); Miss. Reg. 50-018-001(1), -001(2)(C) (LEXIS through 1999) (providing details).	INSTITUTIONS OUTPATIENT	DISEASE STATE CERTIFICATION DISEASE STATE CERTIFICATION	YES YES	DISEASE DISEASE & PATIENT	DSM, all management activities including initiation/prescription for specific disease states. DSM, all management activities including initiation/prescription for specific disease states.	UNLIKELY: Telephone Interview with Harold Stumps, Director of Compliance, Mississippi State Board of Pharmacy (Jan. 13, 2000).
Neb.	YES, and current bill to clarify. NEB. REV. STAT. §71-1,142 (LEXIS through 1999) (defining "provision of pharmaceutical care" to include pharmacists "working in concert" with patients and doctors, where "working in concert" is understood to mean "in accordance with a protocol"); L.B. 797 §§ 171, 188, 219, 96th Leg. 1st Reg. Sess. (Neb. West, WESTLAW through 1999) (carried over to second regular session).	ALL	UNCLEAR	YES	PATIENT	CDTM including monitoring, but not WA-model dependent prescribing. Pending bill is intended to explicitly permit collaborative agreements and to clarify the permissible scope and roles.	UNLIKELY: Although pharmacists in Nebraska are seeking to expand their role in the health care process, they are less interested in <i>prescribing per se</i> , and more interested in being given more authority to select the best drug given the physician's diagnosis; as in many other states, there is concern that increasing access to ECPs may be politically unpopular, and pharmacists are concerned about picketers protesting if the pharmacist wants to provide ECPs. Telephone Interview with Allison Jorgensen, Assistant Executive Director, Nebraska Pharmacists Association (Jan. 14, 2000).

Factors → States ↓	Status of De Jure Collaborative Practice	Settings for the Expanded Pharmacist Practice	Additional Pharmacist Training Required by State or Reg. ^a	Ongoing Patient Relationship w/ Collaborating Doctor	Patient or Disease Specific Protocols	Scope of Authority	Is dependent pharmacist prescribing of ECPs likely soon?
Nev.	YES NEV. REV. STAT. ANN. § 639.0124 (West, WESTLAW through 1999) (defining "practice of pharmacy").	INSTITUTIONS	CERTIFICATION for disease states	YES	PATIENT & DISEASE	DSM, management activities including implementation, monitoring and modification but not WA-model.	UNLIKELY: Telephone interview with Jack Paige, Inspector & Investigator for the North, Nevada State Board of Pharmacy (Jan. 13, 2000).
N.M.	YES N.M. STAT. ANN. §§ 61-11B-1 to -3 (LEXIS through 1999 supplement); N.M. ADMIN. CODE tit. 10 §§ 19.4.18 & 10.11.10 (West, WESTLAW through 1999).	ALL	CERTIFICATION as "pharmacist clinicians." N.M. STAT. ANN. § 61-11B-2(C) (LEXIS through 1999 supplement); N.M. ADMIN. CODE tit. 16 § 19.4.18 (3), (4) (West, WESTLAW through 1999).	NO	NEITHER	WA-model dependent pharmacist prescribing under protocol.	YES, can already occur, just need more protocols. While this dependent prescribing authority is available to pharmacist clinicians, there are only about 30 certified pharmacist clinicians in New Mexico and only about half of those pharmacist clinicians exercise prescriptive authority. Of the pharmacist clinicians with protocols on file, at least two or three are involved in women's health care and have worked with contraceptives; although it is not clear whether their protocols cover the prescription of ECPs, it is agreed that any pharmacist clinician could prescribe ECPs if their protocol so covered them. Telephone interview with David Deneoy, Executive Director of the New Mexico State Board of Pharmacy (Jan. 14, 2000). Also, the requirement that pharmacists be certified as pharmacist clinicians may be a barrier to widespread dependent pharmacist prescribing of ECPs.
N.Y.	NO N.Y. PUB. HEALTH LAW § 3302(26) (LEXIS through Nov. 30, 1999) (defining "pharmacist"); N.Y. EDUC. LAW § 6801 (LEXIS through Nov. 30, 1999) (defining the practice of pharmacy). However, CDTM bill has been introduced.						UNLIKELY: While a bill providing an expanded role for pharmacists has been introduced, it is unclear what the scope of the expanded authority would be, and it is unclear what the ultimate disposition of the bill will be. Telephone interview with Lawrence H. Mokhiber, Executive Secretary, New York State Board of Pharmacy (Jan. 14, 2000).
N.D.	YES N.D. CENT. CODE § 43-15-31.4 (West, WESTLAW through 1999); S.B. 2176, 56th Leg. (N.D. 1999) (enacted) (changing the definition of "practitioner" in section 43-15-01, so as not to specifically exclude pharmacists).	INSTITUTIONS	--	YES	NEITHER	CDTM including initiation, modification, and monitoring, but not WA-model dependent prescribing.	UNLIKELY: see supra Part IV.B.3.b.2

Factors ↑ States ↓	Status of De Jure Collaborative Practice	Settings for the Expanded Pharmacist Practice	Additional Pharmacist Training Required by Statute or Reg. ^	Ongoing Patient Relationship w/ Collaborating Doctor	Patient or Disease Specific Protocols	Scope of Authority	Is dependent pharmacist prescribing of ECPs likely soon?
Ohio	YES OHIO REV. CODE ANN. § 4729.01(B) (visited Feb. 2, 2000) < http://orc.avv.com/title-47/sec-4729/sec-4729.01.htm > (defining the "practice of pharmacy" to include "acting pursuant to consult agreement"); OHIO REV. CODE ANN. § 4729.39(A) (visited Feb. 2, 2000) < http://orc.avv.com/title-47/sec-4729/sec-4729.39.htm > (defining the scope of "consult agreements"); OHIO ADMIN. CODE § 47-29-04 (visited Feb. 2, 2000) < http://onlinemedics.andersonpublishing.com/oc/division-47/chapter-4729/4729-29-04 > (providing details regarding collaboration).	ALL, but less restricted patient specificity in institutions.	NO	YES	PATIENT	CDTM: can create "consult agreements" allowing for outpatient monitoring and modifying (only after contacting and conferring with the doctor); no W-A-model dependent prescribing. Scope may be clarified by upcoming bill that 1) more clearly delineates the differences in authority for institutional and outpatient pharmacists. 2) more clearly defines "contact and confer," and 3) changes the 1 physician/ 1 pharmacist nature of the consult agreement. Telephone interview with Bill McMillan, Executive Director, Ohio State Board of Pharmacy (Jan. 18, 2000).	MAYBE FAR IN THE FUTURE: Ohio APNs are currently fighting for collaborative prescriptive power, so pharmacists have backed off; additionally, Ohio has somewhat a shortage of pharmacists, so it might be difficult to gather the requisite number of people to strongly advocate for dependent pharmacist prescriptive authority. <i>Id.</i>
Or.	YES 40 Op. Or. Att'y Gen. 474 (1980) (interpreting the Oregon Pharmacy Act in OR. REV. STAT. ch. 689 to allow for drug substitution and some drug therapy alteration by pharmacist pursuant to an advance written agreement with a physician); OR. ADMIN. R. 855-006-0010, 855-041-0100 (LEXIS through 1999) (defining CDTM in accordance with the attorney general's opinion).	ALL	NO	YES	PATIENT	CDTM including initiation, modification, and monitoring, but no W-A-model dependent prescribing.	UNLIKELY: The legislature had discussed the issue of ECP access through pharmacist prescribers, but did not take any action; also, while Oregon has been continuing to expand the role of pharmacists, it is unlikely that the role of pharmacists in Oregon will be expanded in the near future to allow for non-patient specific collaborative practice, especially since the recent codification in the regulations of the current scope of pharmacist collaborative practice power was the subject of much controversy. Telephone interview with Larry Martin, Chief Inspector, Oregon State Board of Pharmacy (Feb. 22, 2000).
S.D.	YES S.D. CODIFIED LAWS §36-11-2.2, -19.1 (LEXIS through 1999).	ALL, but institutional is much more common.	NO	YES	NEITHER	CDTM including initiation, modification, and monitoring, no W-A-model dependent prescribing.	UNLIKELY: see <i>supra</i> Part IV.B.3.a.2.

Factors States	States of the Joint Collaborative Practice	Settings for the Expanded Pharmacist Practice	Additional Training Required by State or Reg. ^a	Ongoing Patient Relationship w/ Collaborating Doctor	Patient or Disease Specific Protocols	Scope of Authority	Is dependent pharmacist prescribing of ECPs likely soon?
Tex.	YES TEX. OCC. CODE ANN. § 551.003(33MF) (LEXIS through Dec. 31, 1999); TEX. OCC. CODE ANN. § 157.101(b) (LEXIS through Dec. 31, 1999); 22 TEX. ADMIN. CODE § 193.7 (LEXIS through October 31, 2000); 22 TEX. ADMIN. CODE § 295.13 (LEXIS through Oct. 31, 2000).	ALL	MINIMAL	YES	NEITHER	CDTM including delegation to pharmacist of implementing or modifying drug therapy authority after physician diagnosis, but no WA-model dependent prescribing.	POSSIBLE, BUT UNCLEAR: Under the prior code, a pharmacist could work with a woman's doctor to help her rapidly obtain a prescription for ECPs, however, even this is still a few steps away from the cost-effective, convenient access provided by the Washington model of dependent pharmacist prescribers of ECPs. TEX. REV. CIV. STAT. ANN. art. 4495b, art. 4542a-1 (repealed 1999). Additionally, increasing access to ECPs is likely to be controversial in Texas, so it is unclear how Texans will react to an attempt to increase access to ECPs by using a liberal view of the current scope of pharmacy practice. Telephone interview with Marilyn Pearce, Staff Compliance Officer, Texas State Board of Pharmacy (Jan. 13, 2000).
Vt.	YES The regulation, and not the statute provide for CDTM. VT. STAT. ANN. tit. 26, § 2022 (LEXIS through 1999); VT. CODE R. 4.51Z (1999) (Board of Pharmacy Rule available <http://170.222.200.71/pharmacyrule.htm>)	INSTITUTIONS	-	YES	NEITHER	CDTM including monitoring and some dosage modifications, but no WA-model dependent prescribing.	NO CURRENT PLANS, despite consideration of more expansive collaborative practice. Telephone interview with Carla Preston, Staff Secretary, Vermont State Board of Pharmacy (Jan. 18, 2000).
Va.	YES VA. CODE ANN. § 54-1-3100 (LEXIS through October 1, 1999) (the provision regarding collaborative practice expires as on July 1, 2004).	ALL	UNCLEAR: no regulations yet.	YES	LIMITED: limited to certain diseases or drugs.	CDTM, but scope unclear. Re: 18 VA. REG. CODE 1281, 1296 (LEXIS through 1996) (discussing adopting emergency regulations on CDTM).	UNLIKELY
Wash.	YES WASH. REV. CODE ANN. § 18.64.01(04-11) (West, WESTLAW through 1999); WASH. ADMIN. CODE § 246-863-100 (West, WESTLAW through Jan. 5, 2000).	ALL	NO	NO	NEITHER	Dependent pharmacist prescribing -- pharmacists can "initiate" under protocols.	YES

DSM = disease state management. See *infra* Part IV.B.3.a.1. (discussing the Mississippi model for disease state management).
 CDTM = collaborative drug therapy management (may include one or more of the following: monitor, modify, continue).
 A = Of course, additional educational requirements can be imposed by the protocol. The question posed in this column is whether additional education is required.
 - = no information.
 DSM = disease state management. See *infra* Part IV.B.3.a.1. (discussing the Mississippi model for disease state management).
 CDTM = collaborative drug therapy management (may include one or more of the following: monitor, modify, continue).
 A = Of course, additional educational requirements can be imposed by the protocol. The question posed in this column is whether additional education is required.
 - = no information.

