

# A Tale of Two New Methods

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Applying the lessons learned from emergency contraception to misoprostol for early abortion

**A BRIEFING PAPER COMMISSIONED  
BY THE REPRODUCTIVE HEALTH  
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## PREFACE

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We are at a unique moment in the history of abortion access in the US. On the one hand, we have seen some positive recent developments. For instance, in March the Food and Drug Administration (FDA) approved an updated drug label for mifepristone (“the abortion pill”), bringing the label more closely in line with current evidence and medical practices that have been repeatedly proven safe and effective. A medication abortion protocol of mifepristone followed by misoprostol accounted for nearly one-quarter of non-hospital abortions in 2011, and with the new label even more abortion patients will be eligible for medication abortion. And in June the Supreme Court struck down a highly restrictive abortion law, explaining the decision in part by saying that the law increased the obstacles to getting an abortion “without providing any benefit to women’s health capable of withstanding any meaningful scrutiny.” On the other hand, states enacted 288 abortion restrictions from 2011 to 2015, and in the first half of 2016 state legislators have added another 46 to that tally. Many of these restrictions have combined to shut down or otherwise cut off access to abortion clinics. Moreover, federal and state bans on Medicaid coverage for abortion continue to compound barriers to abortion care for most low-income women.

The confluence of improved technologies (i.e., abortion pills) and increased barriers to clinical care have prompted many in the reproductive health, rights, and justice movement to ask what strategies we can pursue to create new paths to abortion care. In this context, the incidence of what has commonly been referred to as “self-induced abortion” is getting newfound attention. Researchers estimate that between 100,000 and 240,000 women in Texas have tried to end a pregnancy on their own without medical assistance, and there is anecdotal evidence suggesting that this phenomenon has been taking place for years in other states as well. As clinics continue to close, there is both concern that this trend will result in an increase in use of unsafe methods to end an unwanted pregnancy and also hope that some who want to end a pregnancy can procure and use the safe and effective abortions pills that exist today without encountering medical or legal problems.

Many advocates are already working to loosen restrictions on mifepristone and to develop innovations in service delivery, such as telemedicine, to expand the reach of clinical care. Others are examining ways to increase access to abortion pills (either misoprostol alone or mifepristone in combination with misoprostol) outside of a clinical setting, whether as a stopgap for those who cannot access clinical care within a harm reduction model or as an option for those who prefer to manage their health needs under a self-help framework.

The Reproductive Health Technologies Project (RHTP) has been a leader in efforts to introduce both mifepristone and emergency contraceptive pills to the US market. Informed by these experiences, we commissioned this report to assess how lessons from past efforts to expand access to emergency contraception might usefully guide today’s efforts to improve access to medication abortion, and specifically to misoprostol for abortion.

Recognizing certain parallels—and important differences—between emergency contraceptive pills and misoprostol for abortion, we asked the authors to engage in a thought exercise. They applied the lessons learned from the fight to get a dedicated emergency contraceptive product

approved for sale by the FDA and then moved over-the-counter to see if there were important strategies we could use in furthering access to misoprostol.

We recognize that promoting misoprostol alone for abortion is only one strategy among many in the effort to improve access to abortion care generally and medication abortion in particular. For instance, RHTP is fully supportive of – and actively engaged in -- the efforts underway to increase access to mifepristone. We also understand why a combined regimen of mifepristone and misoprostol has been deemed the “gold standard” for medication abortion based on evidence that demonstrates that it is both more effective and, as a general rule, provides a better experience with fewer side effects.

That said, we did not want to risk overlooking alternative strategies that might also contribute to improved abortion access. RHTP’s depth of experience as a bridge among advocates, researchers, providers, industry, funders, and others in efforts to create access to existing and emerging reproductive technologies has taught us that multiple strategies pursued by myriad stakeholders over years, if not decades, are often needed to achieve a common goal.

Our intent for this paper is not to endorse one particular strategy or outcome, but rather to learn from our past in order to inform our future. It is our hope that such an exercise will help stimulate new thinking and approaches to ensuring that those who have decided to end a pregnancy have the tools to manage their fertility and determine the course of their own lives.

Sincerely,

A handwritten signature in black ink, appearing to read "Jessica Arons", written over a horizontal line.

Jessica Arons

President & CEO

Reproductive Health Technologies Project

## INTRODUCTION

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In the early 1990s, reproductive health care providers and advocates were abuzz about the potential for an underused contraceptive technology—emergency contraception—to expand women’s options for pregnancy prevention.<sup>1</sup> The fact that emergency contraception (commonly known as the morning-after pill) could prevent pregnancy if taken just after sex was well known by providers but a “best kept secret” from the women who stood to benefit from its use.<sup>2</sup> Working together to operationalize the potential of this underused method, advocates, foundations, and newly-formed pharmaceutical companies were able to take emergency contraception “from secret to shelf” in the US.<sup>3</sup> Concurrent international efforts were successful in bringing emergency contraception awareness and products to women worldwide. After more than two decades of targeted collaboration, women in 148 countries now have access to dedicated emergency contraceptive products (often over-the-counter) and information about how and when to use them to prevent pregnancy.<sup>4</sup>

Today, another reproductive health technology—misoprostol for early medication abortion—may be the new “best kept secret” in efforts to expand US women’s access to reproductive health care options. But this time it is women themselves who have uncovered the secret. In countries around the world, in particular in countries where safe and/or legal abortion services are not readily available, women have learned that they can take misoprostol on their own to safely end an unwanted pregnancy.<sup>5</sup> In the US, a growing level of self-use of misoprostol by women is causing reproductive health and justice advocates and providers to take a closer look at this potentially game-changing technology for women’s health.

While the two technologies are different in obvious ways—for one, emergency contraception prevents pregnancy and misoprostol ends it—there are many similarities between them. This paper looks at the similarities and differences between the technologies and offers an analysis of how the lessons learned from decades of work bringing emergency contraception to US pharmacy and grocery store shelves might help to inform a strategy for the reproductive health, rights, and justice movement to catch up to what many women around the world, and some women in the US, already know—that misoprostol represents a powerful tool for expanding access to abortion care options. The paper also looks at insights that might be gleaned from the challenges encountered in bringing mifepristone, the other abortion pill, to the US.

This work draws from and expands upon the groundwork that has already been laid with respect to using misoprostol alone for abortion. Gynuity’s 2001 expert convening about misoprostol provided a starting point for discussion. The Misoprostol-Alone Working Group, which was convened by Provide (formerly Abortion Access Project) from 2006 to 2010, continued the

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<sup>1</sup> Trussell, J., & Stewart, F. (1992). The Effectiveness of Postcoital Hormonal Contraception. *Family Planning Perspectives*, 24(6), 262-264.

<sup>2</sup> Hatcher, R. A., Trussell, J., Stewart, F., Howells, S., Russell, C. R., & Kowal, D. (1995). Emergency contraception: the nations best-kept secret.

<sup>3</sup> Foster, A., & Wynn, L. (Eds.). (2012). *Emergency Contraception: The Story of a Global Reproductive Health Technology*. Springer. vii + 323 pp. <http://www.palgrave.com/la/book/9780230102828>

<sup>4</sup> Welcome to ICEC - International Consortium for Emergency Contraception (ICEC). (n.d.). Retrieved August 12, 2016, from <http://www.cecinfo.org/>

<sup>5</sup> Hessini, L. (2013, January 7). *The Power of Pills: Putting Abortion Back in the Hands of Women Around the World*. *Rewire*.

discussion. In 2009, Gynuity and the Reproductive Health Technologies Project (RHTP) co-hosted a meeting that examined the legal issues surrounding women's use of misoprostol for abortion outside of the medical system.<sup>6</sup> Misoprostol-alone was also discussed at a 2013 summit to address the restrictive abortion laws in Texas that was convened by Hampshire College's Civil Liberties and Public Policy Program.<sup>7</sup> Also in 2013, the Public Health Institute, Ipas, and the National Women's Health Network convened a meeting to discuss strategies to put misoprostol in US women's hands as a way to counter increasing restrictions on access to abortion.<sup>8</sup> Most recently, RHTP convened a meeting in December 2015 to discuss all current efforts to improve access to mifepristone and/or misoprostol and to envision a future of unimpeded access to medication abortion.<sup>9</sup>

## METHODOLOGY

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To complement our personal experience with the introduction of emergency contraception, we reviewed the numerous documents and articles that have been written on the history of emergency contraception and abortion pills (including both mifepristone and misoprostol). We also interviewed key informants including medical providers, reproductive health and justice advocates, pharmacists, and researchers with experience in the introduction of emergency contraception or medication abortion to the US market. In many cases, these key informants had worked on both issues, and many are quoted throughout this report.

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<sup>6</sup> Yanow, S. (August 27–28, 2009). The Best Defense is a Good Offense: Misoprostol, Abortion, and the law. Conference Summary and Strategic Recommendations.

<sup>7</sup> National Women's Health Network, (2013). Abortion pills in U.S. women's hands: Bold action to meet women's needs. Report on meeting held on 12/4/13 in Washington, DC. [https://www.nwhn.org/wp-content/uploads/2015/06/Bold-Actions-Meeting-Report\\_Final-2.pdf](https://www.nwhn.org/wp-content/uploads/2015/06/Bold-Actions-Meeting-Report_Final-2.pdf). Accessed November 9, 2015

<sup>8</sup> Ibid.

<sup>9</sup> Reproductive Health Technologies Project, (2015). Yes, And: Multiple Paths to Medication Abortion Success. (On file with author.)

## THE TECHNOLOGIES: A BRIEF COMPARISON

In this paper, use of the term “emergency contraception” refers primarily to the pill form of emergency contraception (which includes several formulations). IUDs inserted after unprotected intercourse also can be used for emergency contraception but are not included in this discussion. The term “medication abortion” refers to using pills to induce abortion, most typically mifepristone used with misoprostol or misoprostol used alone. Because there are multiple technologies for emergency contraception and medication abortion, a brief comparison of their key attributes is provided below.

	<b>Emergency Contraceptive Pills</b>	<b>Misoprostol</b>	<b>Mifepristone with misoprostol</b>
<b>Forms</b>	Pills (three formulations, taken orally up to 3-5 days after intercourse: estrogen and progestin; progestin only; ulipristal acetate)	Pills (taken orally, vaginally, sublingually, or buccally depending on gestation and protocols)	Pills (mifepristone taken orally, followed by misoprostol taken vaginally, orally, or sublingually depending on protocols)
<b>What it does</b>	Prevents pregnancy	Causes abortion	Causes abortion
<b>US FDA approval (brand name)</b>	1998 (Preven) <sup>a</sup> , estrogen-progestin combination 1999 (Plan B) <sup>b</sup> , progestin-only 2010 (ella), ulipristal acetate	1988 (Cytotec)	2000 (Mifeprex)
<b>Approved/labeled indications</b>	Pregnancy prevention after unprotected intercourse	Prevention of gastric ulcers	Early abortion
<b>Generic status in US</b>	Available for progestin-only formulation only	Available	Not yet available
<b>Distribution restrictions</b>	Over-the-counter: progestin-only products Prescription: ulipristal acetate product	Prescription	Available only through certified providers
a. Discontinued b. Now Plan B One-Step			

A graphic showing the highlights in the introduction of these three technologies (emergency contraceptive pills, mifepristone, and misoprostol) is included in the appendix (page 33-35).

## KEY SIMILARITIES

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There are a number of similarities between emergency contraception and misoprostol for abortion, providing opportunities as well as challenges. The most obvious similarity, from the user's point of view, is that both products involve pills that are easy to use and give them greater agency over their reproductive health care. But they also pose challenges; from the provider and advocate point of view, both are considered less desirable than an available "gold standard" product, and both technologies have faced (in the case of EC, successfully faced) the challenges inherent in being used in a way that differs from their original label approved by the US Food and Drug Administration (FDA). These and other similarities are addressed below.

### Opportunities

#### *Both expand the existing options*

Both emergency contraception and misoprostol for abortion expand the options women have to control their fertility. In the case of emergency contraception, the expanded option was important because it provided a new time frame in which a contraceptive method could be used—after sexual intercourse—giving women an extra opportunity to prevent pregnancy when no method was used or a method failed (such as a broken or slipped condom). And because of emergency contraception's unique properties—the fact that it can be used to prevent pregnancy *after* intercourse—this new method significantly expanded the range of methods available. Misoprostol abortion also has the potential to expand women's options, not because it is unique, but because it provides an important alternative to other existing abortion methods. In places where surgical abortion and medication abortion using mifepristone and misoprostol combined are not available or accessible, misoprostol alone can provide women (if they can obtain the product) with a safe and effective abortion method that they can administer on their own.

#### *Both give women agency over their health care*

A key similarity between emergency contraception and misoprostol abortion is the ease of use: They both entail taking some pills by mouth. Because of this ease of use, both medications have the potential of putting control of one's fertility directly in women's hands. As one key informant put it, both emergency contraception and misoprostol are:

...potentially fantastic ways for a woman to have full control over her reproduction—emergency contraception allows a woman to prevent pregnancy, and if she is pregnant she can take medication abortion. The methods give her the agency to take care of it herself, potentially, without needing to visit a doctor.

Much of the work that was done to increase women's agency regarding emergency contraception involved efforts to get dedicated products over the counter (not requiring a doctor's prescription or office visit).

#### *Both have been shown to be safe and effective*

Both emergency contraception and misoprostol for abortion have clear data supporting the efficacy and safety of their use. For emergency contraception, decades of research had

established the safety and efficacy of the combined regimen and data from large multi-center trials conducted by the World Health Organization (WHO) in collaboration with the European pharmaceutical company Gedeon Richter were used to support the FDA application for the levonorgestrel-only product (Plan B). Efforts to seek approval for emergency contraception in the US also benefited from the support of prominent health organizations, including the American College of Obstetricians and Gynecologists (which issued a practice bulletin for emergency contraception in 1996), the American Medical Women's Association, the Association for Reproductive Health Professionals, and the American Public Health Association.<sup>10</sup>

Likewise, much research has been done to demonstrate the safety and efficacy of misoprostol for abortion.<sup>11 12</sup> The WHO's safe abortion guidelines state that, where mifepristone is not available, misoprostol can be used alone to cause an abortion through 12 weeks after the first day of a woman's last menstrual period.<sup>13</sup> The WHO also recognizes that the risk of unsafe abortion lies on a spectrum, and states that medication abortion taken outside the medical system by women who are using correct doses and regimens is safer than other methods women might use when access to care is severely restricted.<sup>14</sup> As with emergency contraception, most of this research was conducted not by pharmaceutical companies but by public sector organizations such as Gynuity Projects, Ibis Reproductive Health, Venture Strategies Innovations, and the WHO.

### *Both are/were being used "off-label"*

Emergency contraception and misoprostol abortion are also similar in that the medications needed for these indications were already approved and available for other indications in the US, making off-label use possible (where political interference has not resulted in restrictions on such use). Advocates for emergency contraception capitalized on this opportunity by promoting the repackaging of daily oral contraceptive pills as emergency contraception and instructing women (and providers) about how to access do-it-yourself emergency contraception using pills from their existing oral contraceptive pill packs. Similarly, the women in Brazil who discovered by reading the label that Cytotec (misoprostol) could cause an abortion did the same—they began "off-label" use and in doing so developed a new abortion method.

In the US today, when misoprostol is used to terminate a pregnancy, it is also being used "off-label"—it is available in pharmacies by prescription for the prevention of gastric ulcers. Like many medications it is also widely used for other off-label indications. Obstetrical uses of misoprostol include first and second trimester abortion, early abortion in combination with mifepristone,

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<sup>10</sup> Pillsbury, B., Coeytaux, F., & Johnston, A. (1999). From secret to shelf: how collaboration is bringing emergency contraception to women.

<sup>11</sup> Consensus Statement: Instructions for Use-Abortion Induction with Misoprostol in Pregnancies up to 9 Weeks LMP. Expert Meeting on Misoprostol sponsored by Reproductive Health Technologies Project and Gynuity Health Projects. Jul 28, 2003. Washington, DC

<sup>12</sup> Moreno-Ruiz, N. L., Borgatta, L., Yanow, S., Kapp, N., Wiebe, E. R., & Winikoff, B. (2007). Alternatives to mifepristone for early medical abortion. *International Journal of Gynecology & Obstetrics*, 96(3), 212-218.

<sup>13</sup> WHO (2012). Safe abortion: technical and policy guidance for health systems – 2<sup>nd</sup> Edition, [http://apps.who.int/iris/bitstream/10665/70914/1/9789241548434\\_eng.pdf?ua=1](http://apps.who.int/iris/bitstream/10665/70914/1/9789241548434_eng.pdf?ua=1).

<sup>14</sup> Ganatra, B., Tuncalp, O., Johnston, H. B., Johnson Jr, B. R., Gulmezoglu, A. M., & Temmerman, M. (2014). From concept to measurement: operationalizing WHO's definition of unsafe abortion. *Bulletin of the World Health Organization*, 92(3), 155-155.

cervical ripening before a surgical abortion, treatment of miscarriage or incomplete abortion, labor induction; and the prevention and treatment of postpartum hemorrhage.<sup>15</sup>

## Challenges

### *Changing role of the provider*

In giving women the potential for full agency in managing their reproductive health needs, both methods also challenge the need for physician involvement in the prescription and administration of the medication. In the early years of the campaign for emergency contraception, despite a growing demand for this new contraceptive option and numerous champions including Drs. Felicia Stewart and James Trussell, many providers remained uninformed about the method or uneasy about prescribing it. A 1997 survey commissioned by the Kaiser Family Foundation showed that, even among clinicians who knew about emergency contraception only 10% routinely counseled women about its use.<sup>16</sup> Despite evidence from smaller studies, the American College of Obstetricians and Gynecologists did not publish a “Practice Bulletin” on emergency contraception until there was data from a large demonstration project (the Pacific Institute’s Kaiser Permanente project in California).<sup>17</sup> The medical community’s hesitancy to let go of control of the product held back changes in medical practice and contributed to the slow pace of progress in moving emergency contraception from a prescription-only product, to “behind-the-counter” (women had to ask a pharmacist for it and meet certain age requirements), to its current status as fully available over-the-counter. Additionally, even when the medical community began to come around, intense political opposition continued and opponents of contraception successfully exerted influence over the regulatory process, delaying OTC access to emergency contraception for decades despite strong evidence of safety.

Efforts to make misoprostol available for abortion will be similarly affected by politics and the perception that clinical oversight is needed to ensure safe usage. At this time, medication abortion in the US lies firmly in the bailiwick of the medical community, both legally and in the minds of most clinicians, many of whom worry that the method will not be used as safely without their assistance. Yet, evidence from around the world suggests that women are able to use medication abortion—both misoprostol alone and mifepristone and misoprostol together—to safely terminate their pregnancies.<sup>18</sup> Indeed, dedicated products are available for medication abortion on pharmacy shelves in many countries and, though a prescription is often theoretically

<sup>15</sup> Allen, R., & O’Brien, B. M. (2009). Uses of misoprostol in obstetrics and gynecology. *Rev Obstet Gynecol*, 2(3), 159-68.

<sup>16</sup> Contraception, E. (1997). *Is the Secret Getting Out*. Menlo Park, CA: Henry J Kaiser Family Foundation.

<sup>17</sup> Pillsbury, B., Coeytaux, F., & Johnston, A. (1999). From secret to shelf: how collaboration is bringing emergency contraception to women.

<sup>18</sup> Ngo, T. D., Park, M. H., Shakur, H., & Free, C. (2011). Comparative effectiveness, safety and acceptability of medical abortion at home and in a clinic: a systematic review. *Bulletin of the World Health Organization*, 89(5), 360-370.

required, women are purchasing and using the products effectively without ever consulting a doctor or pharmacist.<sup>19</sup>

### *Liability concerns regarding off-label use*

Off-label use of drugs—using medications for conditions other than those for which the FDA originally approved the drug—is a common, legal, and accepted practice in the US. And indeed, this alternate use of a registered product was the genesis of both emergency contraception and misoprostol for abortion. Yet, despite this common practice in the medical community, early efforts to introduce emergency contraception were limited by unfounded fears that using oral contraceptives off-label for emergency contraception would potentially open providers to liability.

For example, Planned Parenthood Federation of America initially did not include emergency contraception in its array of contraceptive services because it was concerned that promoting a method that was not approved by the FDA could be a legal liability (Pillsbury et al., 1999). At the same time manufacturers of birth control pills were prohibited by law from marketing oral contraceptives for a non-approved use and, fearing political fallout, had declined to seek FDA approval to add the emergency contraception indication to the labeling of their oral contraceptive products. To address these obstacles, in November 1994, the Center for Reproductive Law and Policy (now the Center for Reproductive Rights), supported by the American Medical Women’s Association, the American Public Health Association, and Planned Parenthood of New York City, filed a Citizens Petition to the FDA.

Citing the scientific evidence and legitimacy conferred upon the method by the WHO, the lead body in research on new methods of emergency contraception, and by the American College of Obstetricians and Gynecologists’ practice guidelines on emergency contraception, the petition requested: 1) that the FDA declare post-coital contraception (as emergency contraception was then known) to be safe and effective; and 2) that the FDA require the pharmaceutical companies to correctly label, in their package inserts, this use of the pills and define the dosage.<sup>20</sup> The FDA took the petition seriously, held advisory committee hearings, and in February 1997 published the historic notice in the Federal Register that declared post-coital emergency contraception safe and effective. It also published the dosage and regimen to be used.<sup>21</sup> This was one of the very few times that the FDA has taken such a step without a request from a pharmaceutical company and it paved the way for bringing to market dedicated products for emergency contraception.

While the promotion of off-label use of misoprostol for abortion may be similarly challenged by fears about liability pertaining to the promotion of an off-label product, the true legal liabilities are likely to be around laws in some states that strictly regulate the provision of abortion, which may

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<sup>19</sup> Harvey, P. (2015). Medical abortion: the hidden revolution. *Journal of Family Planning and Reproductive Health Care*, 41(3), 193-196.

<sup>20</sup> Pillsbury, B., Coeytaux, F., & Johnston, A. (1999). From secret to shelf: how collaboration is bringing emergency contraception to women.

<sup>21</sup> Food and Drug Administration. (1997). Prescription drug products; certain combined oral contraceptives for use as postcoital emergency contraception. *Federal Register*, 62(37), 8610-8612.

impose restrictions related to who provides the abortion and the setting in which an abortion is done (see section on “Legal restrictions on abortion” under Key Differences below).

### *Providing sufficient information*

Effective off-label use of both emergency contraception and misoprostol for abortion depends on the user knowing about its existence, how to access the pills, how to take them correctly (how many and when), and what to expect after taking the pills (both in terms of side effects and effectiveness). As a result, the introduction of both technologies requires effective mechanisms for informing women about the method and how to use it. Messaging challenges related to introducing emergency contraception included: informing women of the existence of this new method, where to obtain the pills (or how to use oral contraceptive pills for emergency contraception), the need to take the pills soon after unprotected sex (within 3 days for some products and 5 days for others), and what side effects to expect. Messaging related to off-label use of misoprostol as an abortion option in the US will similarly require raising awareness about the method, informing women about where to obtain the product, providing instructions for correct usage, and helping women know what to expect after taking the pills. In addition, given the current restrictive legal environment in many states, women will need information about the legality of using misoprostol for abortion outside the health system in their state, what to say if they are asked about misoprostol use (for instance, if they need to seek help for continued heavy bleeding), and how to get legal help if they are prosecuted.

### *Competing with a “Gold Standard”*

Many health care providers perceive both technologies—emergency contraception and misoprostol—as comparing unfavorably to another, more effective option. Efforts to expand access to emergency contraception have consistently been challenged by an underlying concern about the advisability of promoting what many providers viewed as a second-tier choice due to its lower effectiveness compared to ongoing use of routine contraceptive methods.<sup>22</sup> Similarly, misoprostol is viewed as a second-tier option compared to the combined mifepristone/misoprostol regimen, the current “gold standard” of medication abortion methods due to its higher effectiveness and improved side effect profile.

In the case of emergency contraception, advocates overcame the “gold standard” issue by arguing that emergency contraception offered a way to expand women’s options and that women, not providers, should be allowed to decide which of the available contraceptive methods could best meet their needs. In that framework, it was the job of the reproductive health community to help provide access to the product and accurate information so that women could manage their own care, not to decide for women what constituted an acceptable level of risk.

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<sup>22</sup> Coeytaux, F., Wells, E. S., & Westley, E. (2009). Emergency contraception: have we come full circle?. *Contraception*, 80(1), 1-3.

For medication abortion, the combination of mifepristone and misoprostol is currently the standard of care in the US, in large part because it is the most effective regimen;<sup>23</sup> the combination approaches 98% efficacy, whereas misoprostol used alone ranges between 84% to 96% effective.<sup>24</sup> But medical experts, including the WHO,<sup>25</sup> recognize that mifepristone is not always available and, where it is not available, recommend the use of misoprostol alone.

Several of the key informants with whom we spoke argued against actively introducing misoprostol alone for abortion in the US given that the country already has an approved mifepristone/misoprostol regimen. They stressed the greater efficacy and fewer side effects of the combined method and argued that women deserved the best. A few key informants worried that advocating for a “second tier” product could be viewed as lowering the standard of care and endorsing a second class of service for already disenfranchised groups of women. One stated that the availability of misoprostol has the potential to greatly expand access primarily in communities where there is not currently good access to abortion services, such as rural areas and for low-income women and women of color, and therefore introduction efforts could be perceived as providing lower quality services to women who are underserved.

However, other key informants took the opposite tack, noting that an alternative is needed because the combined regimen is unavailable in many parts of the country and expensive when it can be accessed (see sidebar, *Mifepristone: The Promise and the Heartache*). They challenged the notion that the lower effectiveness of misoprostol is significant enough to warrant excluding it as an option, stating, “Why shouldn’t women have a choice if they want to use misoprostol alone?” Many recommended employing multiple strategies—including making a less effective product available—to ensure access to abortion services (see Strategy section below), especially given that efforts to make the mifepristone/misoprostol regimen more accessible in the US are likely to take a long time. As one key informant put it, “It [getting mifepristone over the counter] will take a thousand years. It won’t be in my lifetime with the current political situation.”

### *Addressing the lack of pharmaceutical company interest*

Advocates for emergency contraception set off to bring a “dedicated product” to market, believing that ultimately an FDA-approved product that could be commercially marketed would make emergency contraception more visible and legitimate to women and providers, and ensure better and sustained access to the method. But developing a commercial product proved to be very challenging. Pharmaceutical companies, the usual actors in drug development, viewed emergency contraception as a political “hot potato” and were unwilling to get involved due to fears of anti-choice boycotts that could affect their broader product lines. Ultimately it took a lot of public advocacy and the creation of two pharmaceutical startups with the specific

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<sup>23</sup> American College of Obstetricians and Gynecologists. (2014). Practice bulletin no. 143: medical management of first-trimester abortion. *Obstetrics and gynecology*, 123(3), 676.

<sup>24</sup> Moreno-Ruiz, N. L., Borgatta, L., Yanow, S., Kapp, N., Wiebe, E. R., & Winikoff, B. (2007). Alternatives to mifepristone for early medical abortion. *International Journal of Gynecology & Obstetrics*, 96(3), 212-218.

<sup>25</sup> World Health Organization. (2012). Safe abortion: technical and policy guidance for health systems. WHO.

mission of creating a dedicated emergency contraceptive product to successfully add emergency contraception to women's contraceptive options in the US.<sup>26</sup>

It goes without saying that efforts to develop a “dedicated” misoprostol product (one that has been registered with the FDA and approved for use as an abortifacient) would face similar, if not more acute, challenges than those of emergency contraception. Given that major pharmaceutical companies were unwilling to pursue emergency contraception, their interest in misoprostol as an abortion product seems even more unlikely. For example, although the manufacturer of misoprostol (originally Searle, now Pfizer) cannot prevent its product from being used off-label, the drug owner has taken measures to distance itself from the use of misoprostol for induction of both labor and abortion. In a letter sent to healthcare providers in 2000, Searle warned of serious adverse events when misoprostol was used in pregnant women and noted that the company “promotes the use of Cytotec only for its approved indication.”<sup>27</sup> Lack of industry interest in misoprostol for abortion was cited by experts attending a 2001 seminar as a key obstacle to its expanded use for reproductive health indications.<sup>28</sup> If a strategy to bring a dedicated misoprostol abortion product to market is ever pursued, it will no doubt require the same kind of entrepreneurial pharmaceutical company and foundation support that helped launch dedicated products for emergency contraception.

### *Countering stigma*

Both emergency contraception and misoprostol are burdened with stigma around abortion and notions of sexual responsibility. Early on in the efforts to promote the availability of emergency contraception, advocates had to devote considerable energy to dispelling the notion that emergency contraception reinforced or contributed to irresponsible or promiscuous behavior.

Messages to position emergency contraception as a responsible contraceptive option, or a second chance when “accidents happen” were used to counter the allegations by opponents that access to emergency contraception would lead to moral degeneration or cause women to forgo regular contraceptive use. Yet even among emergency contraception supporters biases about the sexual choices of women who use emergency contraception remain, with some providers being unwilling to prescribe or recommend emergency contraception for repeat use. While the stated concern about repeat use generally is couched in terms of its lower effectiveness compared with other methods, a clear subtext is that women who need emergency contraception more than once are somehow irresponsible.

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<sup>26</sup> Pillsbury, B., Coeytaux, F., & Johnston, A. (1999). From secret to shelf: how collaboration is bringing emergency contraception to women.

<sup>27</sup> Searle, G. D. (2000). Important drug warning concerning unapproved use of intravaginal or oral misoprostol in pregnant women for induction of labor or abortion. *Media Release*, 23.

<sup>28</sup> Shannon, C. S., & Winikoff, B. (2004). *Misoprostol: An Emerging Technology for Women's Health: Report of a Seminar, 7-8 May 2001*, Population Council, New York, New York. Population Council.

The allegation that emergency contraception could possibly be an abortifacient has also posed a persistent problem for its introduction. Organized opposition to FDA approval of dedicated emergency contraceptive products has focused on their purported abortifacient properties, with opponents often equating emergency contraception with the abortion pill and advocates emphasizing the biological mechanism of action to show that the method does not cause an abortion but rather prevents

fertilization. Although the science is quite clear and groups such as the International Consortium for Emergency Contraception have issued numerous evidence-based fact sheets to address this concern, the public perception that emergency contraception causes abortion is still strong. Ironically, while working to counter the misperception that emergency contraception causes abortion, advocates may have inadvertently further stigmatized methods that do cause abortion such as misoprostol.<sup>29</sup>



Most of the informants we interviewed believed that the stigma that exists around abortion in the US will pose an even bigger challenge to the introduction of misoprostol than it did for emergency contraception, given that it is an actual abortifacient. A few thought this stigma was likely too strong to overcome, especially given the current divisive climate regarding abortion, the new legal restrictions sprouting up in many states, and the uncertainty of the outcome of the 2016 elections.

<sup>29</sup> Arons, J. (2015, October 1). Untapped potential of the abortion pill, 15 years later. The Hill. Retrieved from <http://thehill.com/blogs/congress-blog/healthcare/255545-untapped-potential-of-the-abortion-pill-15-years-later>

**SIDEBAR: MIFEPRISTONE—THE PROMISE AND THE HEARTACHE**

2015 marked the 15<sup>th</sup> anniversary of the approval of mifepristone in the United States.<sup>30</sup> While there is much to celebrate—the FDA approval of a non-surgical abortion option providing women with a distinctly different abortion experience and its incorporation into existing abortion services—there is also much to lament. When it debuted, mifepristone was touted as the “moral property of women” and seen by many as a game changing technology. The hope was that having an abortion pill could expand the availability of abortion services into family practice settings and possibly even enable pharmacy or over-the-counter access to abortion, thereby diffusing the stigma around both providing and seeking abortion.<sup>31</sup> There was great hope that having access to a method that could bypass the much-stigmatized abortion clinic would make it possible for women to have a more private abortion experience, one that they controlled themselves.<sup>32</sup> The introduction of mifepristone in the United States has been mired in political controversy.

The introduction of mifepristone in the United States has been mired in political controversy. As a result, over-regulation has prevented it from living up to its potential to increase access.<sup>33</sup> From the outset, the FDA treated mifepristone differently from other drugs. While considering the drug application, it allowed politics to drive a process that had until then been based on scientific evidence. Ultimately, the FDA approved the application but required extraordinary restrictions on the product's use. Specifically, Mifeprex—the US trademark name for mifepristone—was made available only through the manufacturer, not pharmacies. Only physicians were allowed to prescribe Mifeprex, and those who wished to prescribe it were required to enroll in a national registry and provide proof that they are able to assess the duration of pregnancy accurately, diagnose ectopic pregnancies and provide surgical intervention and emergency care as needed (or refer women elsewhere for such care).<sup>34</sup> Patients were required to sign an informed consent form that described a protocol that sometimes differed from the one the provider was using, which could cause unneeded confusion and anxiety for the patient.<sup>35</sup>

Furthermore, political detractors restricted the use of mifepristone in some states, compromising the care women received by passing laws that require providers to adhere to the original FDA label's dosage, even though evidence-based medical practice supported the use of modified dosage, even though evidence-based medical practice supported the use of modified regimens for better effectiveness and fewer side effects.<sup>36</sup> These restrictions remain on Mifeprex, largely unchanged, through an FDA mechanism known as a Risk Evaluation and Mitigation Strategy (REMS).<sup>37</sup> This situation improved significantly in March 2016 when the FDA approved a revised label for Mifeprex. The change brought the drug label in line with evidence and medical practice in several important respects, including the doses for the drugs used in the medication abortion regimen, allowing use up to 70 days gestation and establishing the option for women to take the second drug outside the clinic.<sup>38</sup> Additionally, the FDA updated the Prescriber's Agreement so that

<sup>30</sup> Winikoff, B., & Westhoff, C. (2015). Fifteen years: looking back and looking forward. *Contraception*, 92(3), 177-178.

<sup>31</sup> Coeytaux, F., Moore, K., & Gelberg, L. (2003). Convincing new providers to offer medical abortion: what will it take?. *Perspectives on Sexual and Reproductive Health*, 35(1), 44-47.

<sup>32</sup> Gold, M., & Chong, E. (2015). If we can do it for misoprostol, why not for mifepristone? The case for taking mifepristone out of the office in medical abortion. *Contraception*, 92(3), 194-196.

<sup>33</sup> Mifeprex Label (2004) P. 14. Retrieved August 12, 2016 from [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2004/020687s010-lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2004/020687s010-lbl.pdf).

<sup>34</sup> Report to the U.S. Government Accountability Office: Approval and Oversight of the Drug Mifeprex. U.S. Food and Drug Administration (2008) ;GAO-08-751:20-24. Washington, DC: U.S. Government Accountability Office. <http://www.gao.gov/new.items/d08751.pdf>.

<sup>35</sup> Winikoff, B., & Westhoff, C. (2015). Fifteen years: looking back and looking forward. *Contraception*, 92(3), 177-178.

<sup>36</sup> Coeytaux, F., Moore, K., & Gelberg, L. (2003). Convincing new providers to offer medical abortion: what will it take?. *Perspectives on Sexual and Reproductive Health*, 35(1), 44-47.

<sup>37</sup> Hyman, P., & McNamara, P. C. (2007). Food and Drug Administration Amendments Act of 2007. No. 110–85, § 909(b)(1), 121 Stat 823 (“(1) A drug that was approved before the effective date of this Act is, in accordance with paragraph (2), deemed to have in effect an approved risk evaluation and mitigation strategy under section 505–1 of the Federal Food, Drug, and Cosmetic Act”).

<sup>38</sup> US Food and Drug Administration, Mifeprex Label p. 2-3, [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2016/020687s020lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf).

non-physician clinicians may also register to provide Mifeprex.<sup>39</sup> The FDA left many of the distribution restrictions on Mifeprex outlined in the REMS in place, however, despite the evidence that they create barriers to providing the highest standard of medication abortion care.<sup>40</sup>

While it is too soon to evaluate the effect of the label change on mifepristone's availability in the United States, we know that these restrictions historically limited mifepristone use to facilities that were already providing surgical abortion; in 2011, only 1% of abortions were done through private physicians' offices (as opposed to abortion clinics or hospitals).<sup>41</sup> While some clinics are moving toward allowing women to take the medication at home instead of in the clinic, these providers still require that the women come to the clinic to be evaluated and to be given the pills.<sup>42</sup> In essence therefore, what we have accomplished by bringing mifepristone to the United States, has been to give women who have access to an abortion clinic an important alternative method of abortion—one that does not require a surgical procedure and that gives women a qualitatively different abortion experience. (The Guttmacher Institute reports that in 2011, 36% of abortions before nine weeks' gestation were medication abortions.<sup>43</sup>)

But the approval of mifepristone has done little to improve access for women who cannot get to an abortion provider. The FDA restrictions have also contributed to the perception that medication abortions can only be safely provided in a clinical setting, an assumption that is not supported by evidence from women's successful self-use of medication abortion (including misoprostol alone) around the world.<sup>44</sup> In failing to move medication abortion into a wider variety of settings and to create less medicalized pathways for access, advocates have missed a critical opportunity to increase abortion access, agency, and autonomy for the millions of women living in the United States.<sup>45</sup>

Advocates are working to address some of these limitations. The Coalition to Improve Access to Mifepristone in the U.S. involves numerous partners collaborating strategically to reduce barriers. The Coalition successfully reached its short-term goal of better aligning regulations and practice around mifepristone with the evidence base, and it continues to make the case for the full elimination of the REMS and for pharmacy availability. Meanwhile, partners of the coalition are exploring various service delivery innovations including: telemedicine service delivery;<sup>46</sup> eliminating the clinic visit;<sup>47</sup> labeling improvements;<sup>48</sup> and learning from service delivery models in other countries.<sup>49</sup> Despite the significant improvements to access that the new label ushers in, to achieve further progress will require some transformational changes in how we think about medication abortion services.

<sup>39</sup> U.S. Food and Drug Administration. Mifeprex Risk Evaluation and Mitigation Strategy 2016; NDA #020687, [http://www.accessdata.fda.gov/drugsatfda\\_docs/remis/Mifeprex\\_2016-03-29\\_REMS\\_document.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/remis/Mifeprex_2016-03-29_REMS_document.pdf).

<sup>40</sup> Ibid.

<sup>41</sup> Jones, R. K. and Jerman, J. Abortion Incidence and Service Availability In the United States, 2011. *Perspectives on Sexual and Reproductive Health*. 2014. 46: 3–14.

[https://www.guttmacher.org/sites/default/files/article\\_files/abortion\\_incidence\\_in\\_the\\_united\\_states\\_2011.pdf](https://www.guttmacher.org/sites/default/files/article_files/abortion_incidence_in_the_united_states_2011.pdf).

<sup>42</sup> Chong, E. Frye, L., Castle, J., Dean, G., Kuehl, L. and Winikoff B., A prospective, non-randomized study of home use of mifepristone for medical abortion in the U.S. *Contraception*, 2015. Volume 92, Issue 3, 215 – 219.

<sup>43</sup> Guttmacher Induced Abortion [https://www.guttmacher.org/sites/default/files/factsheet/fb\\_induced\\_abortion.pdf](https://www.guttmacher.org/sites/default/files/factsheet/fb_induced_abortion.pdf).

<sup>44</sup> Chong, E. Frye, L., Castle, J., Dean, G., Kuehl, L. and Winikoff B., A prospective, non-randomized study of home use of mifepristone for medical abortion in the U.S. *Contraception*, 2015. Volume 92, Issue 3, 215 – 219; Lafaurie, M.M., Grossman, D., Toncoso, E., Billings, D.L., and Chavez, S. Women's Perspectives on Medical Abortion in Mexico, Colombia, Ecuador and Peru: A Qualitative Study. *Reproductive Health Matters*. 2005. 13(26), 75–83; Lara, D., Abuabara, K., Grossman, D., and Díaz-Olavarrieta, C. Pharmacy provision of medical abortifacients in a Latin American city. *Contraception*. 2006. 74(5).

<sup>45</sup> Coeytaux, F., Hessini, L. and Allina, A. Bold Action to Meet Women's Needs: Putting Abortion Pills in U.S. Women's Hands. *Women's Health Issues*. November–December, 2015. Volume 25, Issue 6, Pages 608–611.

<sup>46</sup> Grossman, D., Grindlay, K., Buchacker, T., Lane, K. and Blanchard, K. Effectiveness and acceptability of medical abortion provided through telemedicine. *Obstetrics and Gynecology*. 2011 Aug;118 (2 Pt 1):296-303; Grindlay, K.,

## KEY DIFFERENCES

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Emergency contraception and misoprostol also differ in important ways. As with the similarities, some of the differences present challenges that will need to be overcome and others provide opportunities for the introduction of misoprostol. Again much can be learned from the approaches taken in the development of emergency contraception.

### Challenges

#### *Legal restrictions on abortion.*

Perhaps the most significant difference between emergency contraception and misoprostol is that while emergency contraception prevents pregnancy, misoprostol ends it. Because of this, misoprostol is subject to laws regulating the provision of abortion services.

These laws vary from state to state and can be quite restrictive. Recently many restrictions have specifically targeted medication abortion. In 2015 alone, 11 states introduced 20 bills aimed at limiting the use of medication abortion.<sup>50</sup>

A recent review of laws regulating use of mifepristone found that:

- 37 states require prescribers to be licensed physicians,
- 18 states require a physician to be physically present with the patient, thereby prohibiting telemedicine
- 3 states require adherence to the FDA-approved prescribing protocols<sup>51</sup>

This strategic use of laws to limit the use of medication abortion is proof that opponents of legal abortion recognize the promise of this important option. And targeting the clinics and providers in this way has been successful in reducing access to mifepristone in many states.<sup>52 53</sup>

Lane, K. and Grossman, D. Women's and providers' experiences with medical abortion provided through telemedicine: a qualitative study. *Women's Health Issues*. 2013. Mar-Apr; 23(2):e117-22.

<sup>47</sup> Raymond, E., Grossman, D., Wiebe, E. and Winikoff, B. Reaching women where they are: eliminating the initial in-person medical abortion visit. *Contraception*. September 2015, Vol. 92, Issue 3, Pages 190-198; Gold, M. and Chong, E. If we can do it for misoprostol, why not for mifepristone? The case for taking mifepristone out of the office in medical abortion. *Contraception*. September 2015. Vol. 92, Issue 3, Pages 194-196; Abbas, D., Chong, E. and Raymond, E. Outpatient medical abortion is safe and effective through 70 days gestation. *Contraception*. 2015. Volume 92, Issue 3, 197-199.

<sup>48</sup> Foster, A., Jackson, C., LaRoche, K., Simmonds, K. and Taylor, D. From qualified physician to licensed health care professional: the time has come to change mifepristone's label. *Contraception*. September 2015, Vol. 92, Issue 3, Pages 200-202.

<sup>49</sup> Grossman, D. and Goldstone D. Mifepristone by prescription: a dream in the United States but reality in Australia. *Contraception*. September 2015, Vol. 92, Issue 3, Pages 186-189; Coeytaux, F. and Hessini, L. In Our Own Hands: What U.S. Women Can Learn from Self-Use of Medication Abortion Worldwide. *RHRealityCheck*, November 7, 2013.

<sup>50</sup> Center for Reproductive Rights, (2015) A Crucial Option - Medication abortion is safe, legal, and capable of revolutionizing reproductive health care. Available: <http://www.reproductiverights.org/feature/a-crucial-option>. Accessed 10.7.2015.

<sup>51</sup> Guttmacher Institute, (2016) State Policies in Brief: Medication Abortion. Available: [https://www.guttmacher.org/sites/default/files/pdfs/spibs/spib\\_MA.pdf](https://www.guttmacher.org/sites/default/files/pdfs/spibs/spib_MA.pdf). Accessed 8.12.2016

<sup>52</sup> Boonstra, D. (2013). Medication abortion restrictions burden women and providers—and threaten US trend toward very early abortion.

<sup>53</sup> Sheldon, W. R., & Winikoff, B. (2015). Mifepristone label laws and trends in use: recent experiences in four US states. *Contraception*, 92(3), 182-185.

The legal risks to women and providers of misoprostol abortion are difficult to evaluate and quantify, and vary from state to state.<sup>54 55</sup> Although off-label use of a drug is legal, and even encouraged medically where there is a body of evidence supporting safe and effective use (as is the case for misoprostol for abortion), it is unclear whether or how the laws regulating abortion generally would interact with the legality of the use of misoprostol for abortion. Many supporters have been wary of drawing attention to the off-label use of misoprostol for abortion for fear of triggering more restrictive laws.

The more likely legal risk is possible prosecution for performing an illegal abortion; both women and providers may be vulnerable, even in states where abortion is not highly restricted. Although in most states there is no direct legal authority to charge a woman for terminating her own pregnancy, in recent years women in several states (Arkansas, Georgia, Idaho, Indiana, and Pennsylvania) have been charged with or prosecuted for using medication on their own to end a pregnancy or assisting others in doing so. In Arkansas, in addition to charging the woman who ended her own pregnancy, the state also secured convictions of a nurse and friend of the woman who provided her with the drugs to induce abortion and helped her with the procedure. In July 2016, the Indiana Court of Appeals overturned a conviction in a case where a woman ended her own pregnancy, though it allowed the state to prosecute the woman for a lesser charge of neglect of a dependent. Though many of these cases do not end in conviction,<sup>56 57</sup> they prove that women who choose to use pills to terminate their pregnancy, and people who try to help them, face several potential legal risks.

### *Complexity of regimens and need for follow-up care*

Several key informants mentioned that the use of misoprostol for abortion is more complex and follow-up care after misoprostol use is potentially more complicated than that for emergency contraception. With misoprostol, dosages vary based on gestation, as do recommended routes of administration (vaginal, buccal, sublingual, and oral). In addition, the side effects of cramping and bleeding can be disruptive and possibly concerning to women and it may be harder to determine if the treatment was successful.

While these differences pose additional communications challenges—women need correct information about dosage and mode of use of misoprostol, have to be informed about what they can expect and when, and if they need follow up care—it is worth noting that providers initially had similar concerns regarding women’s self-use of emergency contraception. Indeed, a key

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<sup>54</sup> Yanow, S. (2012). Positive legal precedent set in case against a woman who self-induced abortion: a rare victory for women in the United States. *Reproductive health matters*, 20(40), 175-176.

<sup>55</sup> Yanow, S. *The Best Defense is a Good Offense: Misoprostol, Abortion, and the law: Conference Summary and Strategic Recommendations. 27-28 August 2009, Gynuity Health Projects and the Reproductive Health Technologies Project, New York City, New York.* Available at [http://www.rhnp.org/abortion/misoprostol/default.asp\\_1](http://www.rhnp.org/abortion/misoprostol/default.asp_1) accessed 10.7.2015.

<sup>56</sup> Mason Pieklo, J. (2012, September 12). Finally a Limit Is Reached: Ninth Circuit Rules McCormack Can't Be Prosecuted For Her Abortion. *Rewire*. Retrieved August 12, 2016, from <https://rewire.news/article/2012/09/12/finally-limits-reached-ninth-circuit-rules-mccormack-cant-be-prosecuted-her-abortion/>

<sup>57</sup> Jarvie, J. (2015, June 10). Murder charge dropped against Georgia woman who took pills for abortion. *Los Angeles Times*. Retrieved August 12, 2016, from <http://www.latimes.com/nation/la-na-abortion-murder-20150611-story.html>

reason emergency contraception was kept a secret was because providers were worried about the potential side effects (cramping, nausea, and possible vomiting) and the consequences of method failure. But these concerns have not been borne out—women have been able to successfully negotiate emergency contraception with little, if any, involvement of the medical community and are proving to be able to do the same with medication abortion.

## Opportunities

### *New communications platforms*

Since the introduction of emergency contraception in the 1990s, the world has witnessed a monumental shift in communications platforms. These new platforms provide key opportunities to address the challenge of providing information about misoprostol. Princeton University was prescient in recognizing the potential of using technology to improve access to reproductive health information, starting the Emergency Contraception Website in 1994, creating the first health information website well before the World Wide Web was in common usage outside of the university setting. However, most of the communications efforts for emergency contraception relied on then-conventional strategies including a hotline, television and radio public service announcements in selected markets, bus placards, billboards, postcards, and direct mail of clinical guidelines to providers. The huge expense of many of these methods (particularly to achieve sustained messaging) necessitated that advocates limit campaigns to selected audiences and/or roll out information campaigns gradually as funding allowed.



In contrast, today's communications platforms are varied and plentiful (e.g., SMS messaging, Twitter, YouTube, viral web campaigns, etc.), and growing use of smart phones makes them highly accessible. In numerous countries around the world, mHealth technologies—the use of mobile communication devices to provide health information and services—are being used to ensure access to safe abortions in rural and underserved communities by; helping drug sellers and pharmacists forecast use and ensure a reliable supply of misoprostol, providing community health workers with information and the medication in the field, and providing information and support directly to women using misoprostol. New websites with information about medication abortion (including misoprostol alone), such as [howtouseabortionpill.org](http://howtouseabortionpill.org), are demonstrating the power of these communication platforms to reach women.

### *New dispensing options*

Another opportunity is the advent of online pharmacies and telemedicine services. A 2012 survey found that 23 percent of Americans reported buying prescriptions online.<sup>58</sup> The pioneer of using new communications platforms and dispensing options to increase women's access to

<sup>58</sup> FDA (2012). "Buying Medicines Online? Be Wary, FDA Says." FDA Consumer Health Information, U.S. Food and Drug Administration, September 2012. <http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM321495.pdf>. Accessed January 11, 2016.

medication abortion information and pills is the Women on Web website. Women on Web is an international collective that provides virtual counseling about safe abortion with pills, answering thousands of emails every day in many languages from women around the world. Women on Web also provides mail order delivery of medications—mifepristone and misoprostol combined—in countries where abortion is outlawed with costs set on a sliding scale. Unfortunately, Women on Web will not ship to the US because abortion is legal here and it is legal to prescribe mifepristone even though many women do not have functional access to either surgical or medication abortion due to restrictive laws and regulations. In 2015, several online information or ordering sites were launched (including [safe2choose.com](http://safe2choose.com), [womenhelp.org](http://womenhelp.org), and [howtouseabortionpill.org](http://howtouseabortionpill.org)). Like Women on Web, however, none of these services will ship product to the US. In Australia, women in most areas are able to access in-home medication abortion through telephone consultation with the Tabbot Foundation. These successful, convenient, and private methods of accessing medication abortion for home use in other countries can serve as useful models as strategies are developed to increase access to medication abortion in the US.

### *Women leading the way for self-care*

In contrast to emergency contraception, which was largely discovered and promoted by the reproductive health research and advocacy community, the move toward using misoprostol for abortion is being driven by women. It was women in Brazil in the early 1980s who discovered that misoprostol, a readily available drug marketed for the prevention of gastric ulcers, could safely end unwanted pregnancies. Living under very restrictive abortion laws, these women came up with this successful strategy and shared their discovery with other women through word of mouth. Since then, women living in many other countries where the health system fails to meet their needs have learned that they too can go to the pharmacy or drug sellers to obtain misoprostol pills, take them in their own homes (without necessarily interfacing with a health care provider), and successfully end their unwanted pregnancy.<sup>59</sup>

There is now growing evidence that women in the US, many of whom are immigrants from countries where such use is common practice, are also using misoprostol at home to end

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<sup>59</sup> Lara, D., Abuabara, K., Grossman, D., & Díaz-Olavarrieta, C. (2006). Pharmacy provision of medical abortifacients in a Latin American city. *Contraception*, 74(5), 394-399.

unwanted pregnancies.<sup>60 61 62 63 64</sup> Again, this seems to be happening through word of mouth, with women accessing information from friends or from the internet.<sup>65</sup>

This grassroots use could provide a unique opportunity for advocates to flip the paradigm around abortion care from one in which doctors and politics control access to care to one in which women care for themselves with medical support only if needed. The paradigm shift would also create opportunities for new allies in the fight to make abortion more accessible (see below). But this requires recognizing that misoprostol is a safe option and that women can be trusted to use it without having to go through a medical gatekeeper, beliefs that are not universally shared by reproductive health advocates.

### *New allies*

Since the 1990s, when the fight for emergency contraception was largely taking place, the reproductive health movement's advocacy community has greatly expanded and strengthened, both in terms of its increased justice focus and its involvement of a more diverse set of partners. From the beginning, the strategies used to expand access to emergency contraception involved almost exclusively the health sector; the leadership and coalition building involved the "usual suspects"—Planned Parenthood clinics, state-based pro-choice groups, college health centers, and NGOs like the National Women's Health Network and RHTP. Eventually, pharmacists were added as partners.

In contrast, today's well-developed reproductive justice movement presents an excellent opportunity to engage a wide range of partners early on in addressing the many barriers to misoprostol, including product price, public and private insurance coverage, and legal restrictions. The fact that misoprostol could help to address abortion access issues—which disproportionately affect low-income women, rural women, young women, immigrant women, and women of color—may make it particularly attractive to potential partners. And the fact that it speaks to women's agency over their health—this is a woman's method, developed by women, propagated by women, and now being demanded by women—will appeal to a much broader coalition of partners than just reproductive health advocates.

For instance, key informants recommended looking beyond the usual groups involved in abortion advocacy to include those that use a human rights or social justice-based framework,

<sup>60</sup> Deprez, E. E. (2013, July 11). Texas Threat to Abortion Clinics Dodged at Flea Markets. Bloomberg. Retrieved August 12, 2016, from <http://www.bloomberg.com/news/articles/2013-07-11/flea-market-abortions-thrive-as-texas-may-close-clinics>

<sup>61</sup> Grossman, D., Holt, K., Pena, M., Lara, D., Veatch, M., Cordova, D., Gold, M., Winikoff, B. and Blanchard, K., Abortion self-induction in the US. *Reproductive Health Matters*. 2010. 18(36):136–146.

<sup>62</sup> Grossman, D., Garcia, S., Kingston, J., and Schweikert, S. Mexican women seeking safe abortion services in San Diego, California. *Health Care for Women International*. 2012. 33(11):1060-9.

<sup>63</sup> Eckholm, E. A pill available in Mexico is a Texas option for abortion. *New York Times*. July 13, 2013. Available: <http://www.nytimes.com/2013/07/14/us/in-mexican-pill-a-texas-option-for-an-abortion.html>. Accessed September 9, 2015.

<sup>64</sup> Hellerstein, E. (2014, June 27). The Rise of the DIY Abortion in Texas. The Atlantic. Retrieved August 12, 2016, from <http://www.theatlantic.com/health/archive/2014/06/the-rise-of-the-diy-abortion-in-texas/373240/>

<sup>65</sup> Fuentes, L., Lebenkoff, S., White, K., Gerdt, C., Hopkins, K., Potter, J. E., & Grossman, D. (2016). Women's experiences seeking abortion care shortly after the closure of clinics due to a restrictive law in Texas. *Contraception*, 93(4), 292-297.

including groups working on violence against women, access to health care, pregnancy rights, women's self-help methods (including home birth advocates), access to HIV/AIDS medications, and harm reduction strategies for substance abuse. Groups serving youth were also mentioned as potentially powerful partners, given that younger generations have demonstrated skills in information sharing, respect for science-based decision-making, and acceptance of liberal causes (as evidenced by their general levels of support for same-sex marriage and transgender rights). Several informants also recommended including those working on expanding access to medication abortion internationally and the opportunities to transfer lessons learned from international work to the US context.

## STRATEGIES FOR MOVING FORWARD

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Emergency contraception advocates successfully brought an underused technology “from secret to shelf.” The achievement is remarkable not only for the enormity of what was accomplished—we started with informing women about cut up pill packs and now have dedicated emergency contraception products (including third generation products) registered in 148 countries—but also for the creative ways advocates, industry, and funders worked together to make this happen. While there are still significant barriers to overcome, the most important one being cost, the experience demonstrated that working together the reproductive health community has the power and influence to successfully tackle challenges—including a lack of pharmaceutical company interest in a potentially controversial product and a conservative political agenda intent on limiting access to contraception. Given the similarities between emergency contraception and misoprostol, many of the same strategies that proved successful for emergency contraception could also benefit efforts to make misoprostol more widely available for abortion in the US.

At the same time, there are also lessons to be learned from things that did not go smoothly with the introduction of emergency contraception and from the many challenges it still faces. Three worthy of comment are:

- the introduction of emergency contraception largely followed a medical model, first involving clinicians and then pharmacists as access points (gatekeepers) to the technology, thus medicalizing a method that could have been a self-help tool;
- the dedicated, over-the-counter emergency contraception product that we have ended up with may not represent a significant advance from our starting point (cut up oral contraceptive pill packs) in that it is expensive and not typically covered by insurance; and
- political opposition to emergency contraception proved to be so strong that it took decades for the advocacy community to achieve its goal of over-the-counter access to a dedicated product.

As advocates move forward with strategies to make medication abortion more available to women, it will be important to consider how to sidestep these pitfalls.

A main overarching strategy used by emergency contraception advocates was the development of broad coalitions—strategic partnerships to share information, coordinate strategies, and generate consistent messaging. The American Society for Emergency Contraception played a key role in fostering information sharing and partnerships by organizing an annual “EC Jamboree” and hosting a listserv for updates about research, program strategies, and advocacy around the country. Partnerships with the pharmaceutical industry were also instrumental in getting a dedicated product on the market; industry representatives regularly attended advocate meetings and advocates worked to support industry through demand generation and policy work. Partnerships also proved useful for securing funding for a coordinated approach. For example, seven organizations with complementary skills banded together to form the Consortium for Emergency Contraception, which jointly raised funds to create and introduce a dedicated product for emergency contraception through demonstration projects in four

countries. Such partnerships could be similarly powerful in expanding access to misoprostol in the US to facilitate efforts among organizations working at the national level as well as within and among state-based coalitions. A coordinated approach would help support information sharing and strategy implementation as well as help facilitate responses to opposition or problems that arise. State-based coalition work was noted as being particularly important given that states have the ability to regulate health care.

A second overarching strategy used by emergency contraception advocates was to simultaneously pursue multiple avenues for expanding access to the method. These included public information campaigns, a hotline, a website to educate women on how to “do-it-yourself” using daily oral contraceptive pills, repackaging oral contraceptives, “advertising” emergency contraception within a health care system (Kaiser Permanente), creating materials for providers, advocating for advance prescription, utilizing pharmacy access systems, registering a dedicated product, and pursuing over-the-counter status. The various approaches were often complementary and some set the stage for later successes; for instance, pharmacy access models (through which women could obtain pills directly from a pharmacist and skip a doctor’s visit) provided useful experience that helped to support eventual over-the-counter approval. The strategy of pursuing multiple avenues toward availability also acknowledged that some avenues, like providing information, gave women the ability to use the technology immediately while others, like product registration, could take considerable time to come to fruition.

It would be wise to pursue multiple strategies when promoting access to misoprostol, as working on multiple approaches simultaneously would increase the chances of success. Based on the lessons learned from the emergency contraception experience, we propose considering three distinct strategies that could be pursued simultaneously:

1. Support women’s self-care with misoprostol;
2. Facilitate access to misoprostol through the medical community; and
3. Pursue the development of a dedicated misoprostol product (or other drug products).

How women could potentially access misoprostol would differ in each of these strategies (see figure below).



## Support women’s self-care with misoprostol

This strategy starts with where we are now, with some women already accessing and using misoprostol for abortion. The strategy would be to support this use by raising women’s awareness of misoprostol as an option, providing access to reliable and legitimate information (both medical and legal) about misoprostol use, and facilitating self-access to the product. This strategy requires a paradigm shift in which advocates and providers let women lead, trusting them to make decisions that benefit their health, learning from them what they need, and responding appropriately. The goal of this strategy would be to “get out of women’s way”—facilitating access to misoprostol without constructing barriers to use. While the example provided here specifies misoprostol, this strategy could also be applied to the combined mifepristone/misoprostol regimen, as evidence suggests women in the US are also accessing these products for self-care.

### *Raise awareness of the option*

For women to use misoprostol, they must first know it exists as an option. One strategy for raising awareness is to capitalize on women’s outrage about lack of access to the product. Efforts to introduce emergency contraception tapped into women’s sense of outrage that there were safe, effective products available that they did not know about and/or have access to. In particular, advocates highlighted that access to emergency contraception was being limited by politics, with regulatory and other decision makers ignoring the scientific and medical evidence in support of making the method more widely available. Public service announcements generated by groups such as RHTP helped build a wave of public interest that made it possible for a new company—Women’s Capital Corporation—to obtain public funding from foundations including Packard, Hewlett, and Compton for the development of Plan B. And it was public outrage that was behind then-Senator Hillary Clinton’s refusal to approve the new head of the FDA until the Agency stopped dragging its feet on the pending application to approve Plan B for use in the US.



Several key informants suggested that the fact that misoprostol is much more readily available (and safely used) in other countries could be used to generate outrage around US access. The same is true for mifepristone, which is becoming much more easily available in many countries (including through pharmacies, many of which do not require a prescription). Most people in the US are likely unaware that women in other countries have much easier access to medication abortion methods than women here. Pointing out this discrepancy and educating the public about the fact that the US lags behind most countries in accessing this important technology,

including countries considered to be much less “technically advanced,” might incite a sense of unfairness that could be harnessed to build demand for equal access. (It is worth remembering that outrage over the fact that RU486 (mifepristone) was available in France but not the US was the genesis of the RHTP.)

To date, most of the work to publicize misoprostol as an option for self-care has been done through blogs and opinion pieces, a format that offers advocates a high degree of control over how the information is framed. Some key informants suggested also working with the popular media to achieve more widespread awareness of US women’s lack of access to this potential self-care method. An excellent example would be working with Lady Parts Justice, a “cabal of comics and writers exposing creeps hell bent on destroying access to birth control and abortion.” Such “outside the box” media partners could prove particularly effective in reaching a wide audience and generating outrage about the lack of access to medication abortion options in the US.

### *Provide information about use and legality*

To use misoprostol effectively, women need accurate information about when and how to use the pills, what to expect after taking the pills, and when to seek follow up care. In the US, we know that women are already using communications technologies, and the internet in particular, to look for and share information about misoprostol. While some good information is available on the internet (for instance, Women on Web has excellent information and often appears at the top of search engine results), reliable websites about using misoprostol alone can be hard to find using common search terms.<sup>66</sup> In addition, many links that mention misoprostol abortion contain misinformation and highly-visible websites that US women may visit to seek information about abortion (such as Planned Parenthood and NARAL) do not include any information about misoprostol-alone abortion, which could lead women to question whether it is a legitimate method. Women also may want information about the legal status of using misoprostol outside the formal health system and how to navigate any legal risks it may involve.

Used strategically, the internet could be a helpful tool for reproductive health, rights and justice organizations to help women make informed, safe choices about their abortion options and gain access to this form of abortion, particularly in areas where access to abortion is restricted by laws or lack of providers. Other forms of media also could be used to reach women. However, some key informants were concerned that a highly visible media campaign, such as was done for emergency contraception, might put those who have used or provided abortion pills in legal jeopardy or lead authorities to clamp down on access to misoprostol. To address this, they suggested a low-key campaign that might be couched in other terms to somehow subtly get the word out (e.g., an education campaign around miscarriage management). Other ideas included:

- A branded national campaign for misoprostol abortion, such as *Back Up Your Birth Control* was for emergency contraception;

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<sup>66</sup> Wells, E., Nichols, V. and Coeytaux, F. (2013). Surfing for Abortion: A brief assessment of the online availability of misoprostol information and pills in the United States. *Public Health Institute*.

- Working with organizations that have top-ranked websites (like Planned Parenthood) to include accurate information about misoprostol (and/or links to Women on Web);
- Hotline(s), particularly to address women's need for information about side effects and when to seek follow-up care;
- Texting services that could help to answer women's questions in real time; and
- Leveraging the information dissemination networks that local reproductive health and justice organizations already have in their communities.

*Facilitate self-access to the product*

A key challenge for women using the self-care strategy is getting the pills. We know that women are accessing and using misoprostol (as well as mifepristone) without being under a clinician's direct care in the US, but we have limited information about the sources of the pills and any problems they have encountered in obtaining them. Some women may be able to get misoprostol from friends who have prescriptions for other indications. Others may seek the product online; some online pharmacies appear to ship misoprostol to the US (some stating (incorrectly) that no prescription is needed).

However, drugs sold from websites are not uniformly reliable and women obtaining medications through these avenues may fall victim to fraudulent companies that misuse credit card information or provide a substandard product, creating a situation of uncertainty for women who use this option. Roles for advocates could include:

- Learning from women about sources of supply of misoprostol and sharing this information with others
- Identifying and verifying online pharmacies that ship misoprostol to the US
- Establishing alternate supply mechanisms (such as a pill bank, where people donate products to be withdrawn by others when needed)



## Facilitate access to misoprostol through the medical community

When emergency contraception was first publicized as an option, it immediately became clear that accessing the pills on the tight time frame for effectively using them (3-5 days) would be challenging if women were required to first visit a clinic for a prescription and then get the prescription filled at a pharmacy. As such, advocates sought ways to work with the medical community to improve timely access. Many of the same strategies that worked for emergency contraception might also be applied to accessing misoprostol via off-label prescription, including:

- Off-label prescription during an office visit
- Off-label prescription by telephone (without an office visit)
- Advance off-label prescription (during a routine care exam or by telephone)
- Pharmacy access (through collaborative agreement or other mechanism in states that allow it)
- Lock box access to medication (after a phone consultation/payment)
- Telemedicine (ideally, similar to the Women on Web approach or the Tabbot Foundation in Australia, a nationwide telephone consultation service for home termination of pregnancy using mifepristone.)

This strategy represents a middle ground option that would require enlisting the partnership of bold providers willing to prescribe without imposing too many restrictions on women. It could be immediately implemented as it works within the existing medical structures and may adhere to current laws and practices depending on the state. However, there are two important caveats: if the goal is to significantly increase access to abortion for women in the US who currently do not have such access, it would require involving a large number of new providers, with a focus on underserved and restricted areas. And it would require considerable effort to identify sufficient numbers of bold providers, as the medical community tends to not easily embrace new and politically controversial practices.

## Pursue the development of a dedicated product

Although both the international and domestic efforts to expand access to emergency contraception employed multiple strategies, perhaps the most important one for creating sustained access was pursuing registration of a dedicated product. As predicted by advocates, having dedicated products for emergency contraception has legitimized the method among both women and providers, and allowed the method to be incorporated into established distribution networks (first by prescription through clinical service sites and now over-the-counter at both clinical and retail sites). But there were numerous costs to this strategy—women lost agency for years because of FDA politics, and the product is now several orders of magnitude more expensive than what it was when we were cutting up birth control pill packs.

Thus, a key strategy decision for expanding access to medication abortion is whether to pursue FDA approval of a dedicated product that could be positioned as being complementary to the currently approved mifepristone/misoprostol regimen. And determining how to position a product on the continuum of care and the exact product to put forward are key components of that decision.

### *Position the technology on the continuum of care*

The unique timing for use of emergency contraception—immediately after unprotected sex—meant that it was an addition to existing options rather than a replacement or competitor to existing products. A number of advocates have suggested that misoprostol could be similarly positioned on the continuum of care: for use in menstrual regulation/induction.<sup>67 68</sup> Women currently have access to methods to prevent pregnancy (contraception) and methods to terminate a recognized pregnancy (abortion). However, there are no approved options in the US to induce menstruation when a woman’s period is late but before a pregnancy is confirmed. This has existed for decades in Bangladesh using vacuum aspiration, referred to as menstrual regulation, and now in a number of African countries and in Mexico where women describe their use of misoprostol as a method to bring down their period or “*bajar la regla*.” Positioning misoprostol in this niche could help it gain status as a new method (that fills a gap in the continuum of care) without setting it up to compete directly with other methods (like mifepristone or surgical abortion). This “new” indication may be an attractive niche for an industry partner. This positioning also makes sense given that misoprostol is more effective when used early in pregnancy. And it capitalizes on ways women already view their options. As one key informant put it, positioning misoprostol as a menses inducer is “a fantastic idea that’s really in sync with how lots of women think about their periods. Women don’t necessarily want to know if they are pregnant, they just want their period back. This is a powerful strategy—women would embrace it.”

<sup>67</sup> Nichols, V. and Coeytaux, F. (2014, February 7). Plan C: The Safe Strategy for a Missed Period When You Don’t Want To Be Pregnant. *RHRealityCheck*. Retrieved August 12, 2016, from <https://rewire.news/article/2014/02/07/plan-c-safe-strategy-missed-period-dont-want-pregnant/>

<sup>68</sup> Arons, J. (2015, October 1) Untapped potential of the abortion pill, 15 years later. *The Hill*. Retrieved August 12, 2016, from <http://thehill.com/blogs/congress-blog/healthcare/255545-untapped-potential-of-the-abortion-pill-15-years-later>.

*Determine the best product to meet the need*

Whether misoprostol is the best product to pursue for FDA approval is another topic for discussion. Other dedicated product strategies might include requesting that the FDA lift its restrictions on distribution of mifepristone, seeking approval of a combined mifepristone/misoprostol product for abortion, requesting an over-the-counter indication for mifepristone or for a combined product, and/or applying for approval for a combined mifepristone/misoprostol product for menstrual induction. Repositioning this existing product—which is more effective and has fewer side effects than misoprostol—might be faster than developing a new misoprostol product. But mifepristone may already be so mired in politics in the US that such an approach would not be feasible.

Questions to consider include:

- What are the implications for cost and access of seeking FDA approval (for over-the-counter status for mifepristone or an abortion indication for misoprostol)?
- What is the status of the clinical evidence base for misoprostol abortion/menstrual induction?
- What data are available/still needed to apply for FDA approval of a dedicated product for either misoprostol abortion or menstrual induction?
- Who are possible industry partners for a generic product (for misoprostol and/or mifepristone)? Or a new indication (such as a pill for menstrual induction)?
- Is OTC approval politically feasible? Financially feasible?
- How can we control pricing so that the resulting product is accessible to women?

Perspective on many of these issues can be gained by looking at the work of organizations such as DKT and Marie Stopes International, which have very successfully introduced mifepristone/misoprostol and misoprostol-alone products in countries around the world.

## CONCLUSION

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Medication abortion, be it with misoprostol used alone or in combination with mifepristone, has the potential to significantly increase women's access to abortion in the US. But we believe achieving meaningful access to medication abortion will necessitate a radically different approach, one that acknowledges that given adequate information and access to a product women can use the method safely and effectively without intervention from a health care provider. In this approach, providers and advocates must see themselves as supporters of women rather than providers of services. Although this paradigm shift to give women the means to care for their own reproductive health will likely unsettle some providers and regulators, it has already been proven feasible by women around the world.

We believe that ultimately women should have full, over-the-counter access to medication abortion for early abortion (or menstrual induction) in the US. We recognize that achieving this goal will not be easy, will require incremental steps, and will need to be done carefully to avoid compromising current access to services. The experience with expanding access to emergency contraception suggests change is possible and that there are many points of opportunity available to us, including a product that meets women's needs, medical science supporting the safety and efficacy of medication abortion, strong and diverse allies who know the power of collaboration, robust communications technologies, and a rapidly shifting landscape of support for progressive causes. Now is the time for the reproductive health community and its allies to help the US raise its standard of care and ensure that US women have access to a full range of options for managing their fertility.

## AUTHORS

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**Francine Coeytaux**, MPH, has over 40 years of experience in the development and evaluation of reproductive health programs. Ms. Coeytaux has worked to promote comprehensive reproductive health services, including abortion, and is best known for her work on new reproductive technologies. She has published and lectured extensively and has pioneered the use of acceptability research to give voice to women and include their perceptions in the shaping of public health agendas. Specifically, she has played an important role in promoting the development of emergency contraception, medical abortion and microbicides - products women can use to protect themselves from unwanted pregnancies, sexually transmitted diseases and HIV/AIDS. In addition to her international experience, Ms. Coeytaux has worked for many years in California and in the US. She helped found the Pacific Institute for Women's Health and the RHTP, both of which played key roles in the development of emergency contraception and in advocating for medication abortion. She has been personally involved in the introduction of both technologies, in the US and internationally, and has written extensively on both topics.

**Elisa Wells**, MPH, is a public health specialist with 25 years of experience in evaluation, training, strategic program development, and program management of reproductive health programs, both in the US and abroad. Ms. Wells has been a champion of emergency contraception since the mid-1990s, when she developed client materials for Kaiser Permanente's repackaging project and a comprehensive information packet for US healthcare providers. She spearheaded an innovative approach to distributing emergency contraceptive pills through pharmacies in Washington State, which was later replicated in other states, and helped manage the Emergency Contraception Website and Hotline. Ms. Wells was also a founding member of the International Consortium for Emergency Contraception, serving as its Coordinator from 1998 to 2001, and has served on the Steering Committee of the American Society of Emergency Contraception. Her experience also includes medication abortion, having worked with Felicia Stewart to produce some of the first medical guidelines for US providers and with the Abortion Access Project to expand provision of medication abortion by advance practice clinicians in Alaska.

## APPENDIX – HIGHLIGHTS OF INTRODUCTION

### Science

Emergency Contraception	Mifepristone (in combination with misoprostol)	Misoprostol (used alone)
<b>1970s</b> “Morning After Pills” (using pills from oral contraceptive packs) start to be used by some doctors and on college campuses.	<b>1980</b> Roussel-Uclaf develops mifepristone, which the company called RU-486	<b>1980s</b> Researchers begin to document women’s self-administration of misoprostol for early abortion
<b>1992</b> Publication of two seminal articles that make the case for EC	<b>1988</b> Mifepristone registered in France and China	<b>1990s</b> Research on misoprostol for women’s health indications expands rapidly
<b>1990s</b> The National Institutes of Health develops and begins testing a new drug that works as EC, ulipristal acetate	<b>1991</b> Mifepristone registered in UK	<b>2000</b> Self-use of misoprostol alone in US begins to be documented
	<b>1992</b> Mifepristone registered in Sweden	<b>2012</b> Self-use of misoprostol alone in US begins to be documented
	<b>1994-</b> Roussel Uclaf gives US drug rights to Population Council and US clinical trial conducted	<b>2015</b> WHO publication recognizes women as capable of safely providing their own abortions with misoprostol
	<b>1999</b> Mifepristone registered in 13 additional countries, but still not the US	
	<b>2007</b> Medabon, first dedicated product containing both mifepristone and misoprostol pills, launched in Nepal and now registered in 40 countries (but not US)	

## Advocacy

Emergency Contraception		Mifepristone (in combination with misoprostol)		Misoprostol (used alone)	
<b>1994</b>	Emergency Contraception Website launched at Princeton	<b>1988</b>	French Minister of Health declares RU-486 the “moral property of women”	<b>2003</b>	Gynuity Health Projects and Reproductive Health Technologies Project convene an expert meeting looking at the use of misoprostol for abortion induction
<b>1994</b>	Citizen’s petition filed with FDA	<b>1988</b>	RHTP founded to provide public education and build public understanding about the French “abortion pill” RU 486	<b>2006</b>	Misoprostol-alone Working Group formed
<b>1996</b>	Emergency Contraception Hotline launched by RHTP	<b>1988-2000</b>	Ongoing advocacy by multiple groups over the next 12 years to encourage US introduction of RU-486	<b>2008</b>	Women on Web includes instructions for misoprostol-alone abortion
<b>1998</b>	Pharmacy access piloted in Washington State	<b>2006</b>	Women on Web goes online, includes instructions for use and mail-order of the drugs to countries where abortion is restricted (but not the US)	<b>2009</b>	Advocates meet to discuss self-use of misoprostol for abortion: <i>The Best Defense is a Good Offense</i>
<b>2000</b>	Pharmacy access expanded to California and eventually to nine states	<b>2010</b>	Advocates address a spike in restrictions on abortion, including an increase in state laws that focus on restricting access to medication abortion	<b>2013</b>	Advocates meet to discuss self-use of misoprostol for abortion, College/Texas
<b>2001</b>	Fight for OTC status begins in with a Citizen’s Petition to the FDA.	<b>2015</b>	Coalition to Improve Access to Mifepristone formed with the goals of aligning the drug label with evidence and practice and eliminating medically unnecessary restrictions on distribution	<b>2013</b>	Advocates meet to discuss self-use of misoprostol for abortion, “ <i>Bold Actions</i> ”
<b>2014</b>	Full OTC status for levonorgestrel products finally achieved after over a decade of FDA hearings, congressional maneuvering, and legal action			<b>2015</b>	RHTP convenes meeting of researchers, providers and advocates to explore growing interest in self-induction and use of medication abortion outside a clinical context
<b>2016</b>	Maryland enacts a law requiring insurance coverage for OTC contraceptive medications, including EC, a step toward making EC more affordable				

## FDA Decisions

	Emergency Contraception	Mifepristone (in combination with misoprostol)	Misoprostol (used alone)
<b>1997</b>	FDA declares EC safe and effective with Federal Register notice	<b>1989</b> FDA bans importation of RU486 for personal use	<b>1988</b> Cytotec (misoprostol) approved for prevention of gastric ulcers
<b>1998</b>	Preven (first dedicated EC product) approved	<b>1996</b> Population Council submits New Drug Application to FDA	<b>2002</b> Generic misoprostol products approved
<b>1999</b>	Plan B (levonorgestrel product) approved	<b>2000</b> FDA approves Mifeprex for US with limits on distribution	<b>2012</b> Generic misoprostol products approved
<b>2003</b>	Two FDA advisory panels recommend granting OTC status	<b>2016</b> FDA approves updated Mifeprex label	
<b>2004</b>	FDA denies petition citing concerns about adolescent use and potential increases in promiscuity		
<b>2006</b>	Plan B approved OTC for 18 and older		
<b>2010</b>	ella (Ulipristal acetate) approved for prescription use only		
<b>2011</b>	FDA recommends that Plan B One-Step be available over the counter without age restrictions but Health and Human Services Secretary Kathleen Sebelius rejects the FDA's recommendation		
<b>2013</b>	FDA approves full OTC access for Plan B One-Step with no age or point-of-sale restrictions		
<b>2014</b>	FDA approves generic one-pill EC products for OTC sale		