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Normalizing the exceptional: incorporating the “abortion pill” into mainstream medicine

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Abstract

Mifepristone, also known as RU-486, and in the US known as “the French abortion pill”, finally received FDA approval in the United States in September 2000. This paper discusses the steps now in process to integrate this drug into mainstream healthcare and the sociological implications of those efforts. Each of the steps that is normally taken to introduce a newly approved medication in the US context is rendered highly complex in the case of mifepristone—because of the unique circumstances of abortion in both American culture generally, and medical culture specifically. The story of RU-486/mifepristone, as it is currently unfolding, can be understood as one of attempting to “normalize the exceptional”. After offering a brief historical overview of the protracted struggle for FDA approval of mifepristone in the US, this paper discusses the typical processes for integration of a newly approved medication into mainstream medicine and contrasts this process with the special challenges posed by a drug that is associated with abortion. We outline the challenges to implementation, including both external and internal obstacles. We compare the traditional role of a pharmaceutical company in drug diffusion and the circumstances of the company that produces mifepristone in the US. We discuss such external obstacles as the conflict between the FDA-approved regime and an evidence-based alternative; the necessity for physicians to order and dispense this drug; the ambiguity over the need for ultrasonography; and insurance reimbursement, malpractice, and other legal issues. Internal issues addressed include “turf issues” between medical specialties and between physicians and advanced practice clinicians as well as concerns over “cowboy medicine”, and patient compliance. This paper concludes with an exploration of the sociological implications of this effort to “normalize the exceptional”.

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Introduction

Mifepristone, also known as RU-486, and in the US known as “the French abortion pill”, finally received US Food and Drug Administration (FDA) approval in the United States in September 2000. This paper discusses the steps now in process to integrate this drug into mainstream healthcare. Each of the steps that is

normally taken to introduce a newly approved medication in the US context is rendered highly complex in the case of mifepristone—because of the unique circumstances of abortion in both American culture generally, and medical culture specifically.

The story of RU-486/mifepristone, as it is currently unfolding, can be understood as one of attempting to “normalize the exceptional”. Abortion is widely acknowledged as the most divisive of all social issues in American society (see Beckman & Harvey, 1998; Luker, 1984; Petchesky, 1984; Rubin, 1994; Solinger, 1998). To list just some indicators of this exceptional status: seven

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members of the abortion providing community have been murdered and thousands of others terrorized at their workplaces (NARAL, 2001); and abortion provision receives more legislative scrutiny than any other branch of medicine,¹ as evidenced by the ongoing high profile Congressional battle over so-called “partial birth abortions”, the involvement of Congress in standards for abortion training in residency,² and, as we discuss below, the fortunes of mifepristone itself being inextricably connected to presidential politics.

Abortion furthermore, is also highly contested *within* medical culture as well. The training in abortion in obstetrics and gynecology residency programs has long been inadequate, with very few residencies routinely providing such training for first-trimester abortions, and even fewer for second-trimester procedures.³ The well-documented shortage of surgical abortion providers—estimated at about 2000 in the US (Henshaw, 1998)—is only expected to get worse as the current generation—disproportionately in their 50s and older—heads toward retirement (Grimes, 1992). And of course, there is the often-repeated fact of only 14% of US countries having an abortion provider (Henshaw, 1998). There are active “pro-life” caucuses within the American College of Obstetricians and Gynecologists (ACOG) (American Association of Pro-Life Obstetricians and Gynecologists, 2001) and in other medical organizations as well

¹In the last 6 years, state legislatures have enacted 264 anti-choice measures. In 2000, 435 anti-choice legislative measures were considered by state legislatures; a total of 45 measures were enacted by 23 states during this time. These regulations fall into several broad categories: attacks on minor’s rights, funding for “fake clinics”, fetal protection legislation, funding limitations, informed consent and waiting period requirements, medical abortion legislation, conscience clause legislation, bans on abortion procedures, and care delivery regulations (NARAL, 2001).

²In 1995, after extensive consultation within the medical profession, the American Council of Graduate Medical Education approved new standards for obstetrics and gynecology residencies requiring training in abortion and the management of abortion complications. The strength of these requirements was severely mitigated when, in an unprecedented move, Congress stepped in and passed a law prohibiting such training requirements (Hodgson, 1998).

³According to a 1991–1992 survey of program directors of obstetrics and gynecology residency programs, only 12% of programs provide routine training in first-trimester and 7% in second-trimester abortion (MacKay & MacKay, 1995). A study conducted in 1998 by the National Abortion Federation of residency programs in obstetrics and gynecology found that 46% of programs routinely offered first-trimester training and 29% offered second-trimester training (Almeling, Tews, & Dudley, 2000). The authors, however, urge caution on interpreting these results because of the low return rate. See also Landy and Steinauer (2001) for a discussion of the authors’ failure to define “routine”.

(National Pro-Life/Pro-Family Organizations, 2001). The recent spate of hospital mergers, with many community hospitals joining with Catholic-controlled health care systems has reduced the prospects of hospital-based abortions which now constitute only an estimated 7% of all abortions in the US (Henshaw, 1998).

But perhaps the most fundamental challenge to the “normalization” of mifepristone is the longstanding stigma of abortion provision within US medical circles—even among the overwhelming majority of physicians who consider themselves “pro-choice” (Joffe, 1995). As one of us has documented at length elsewhere, since the *Roe v Wade* decision in 1973, abortion provision has been marginalized from mainstream medicine. The majority of abortions now take place in freestanding clinics, and most American physicians having little direct experience with abortion services (Joffe, 1995).

After offering a brief historical overview of the protracted struggle for FDA approval of mifepristone in the US, this paper will discuss the typical processes for integration of a newly approved medication into mainstream medicine and contrast this process with the special challenges posed by a drug that is associated with abortion. The materials on which this paper has drawn were collected as part of a larger ongoing project by the two authors who are tracking the spread of mifepristone, and include observations made at professional meetings at which this drug has been discussed; interviews with key individuals involved with training and setting protocols in the use of mifepristone; health care providers who have used the drug, and other figures in the medical world with an interest in the dissemination of mifepristone; and examination of numerous documents pertaining to the medication.

Historical background

Mifepristone, then known as “RU-486”, was discovered by a team of French scientists, led by Etienne Balieu, and became available to French women in 1988. Mifepristone is an antiprogesterin, which alters the uterine lining and disrupts attachment of a fertilized egg; it is used in combination with another drug, a prostaglandin, which causes the uterus to contract and expel the products of conception (Stewart, Wells, Flinn, & Weitz, 2001). In short, if used early in pregnancy (from 7–9 weeks gestation), this drug regime promised to offer women a non-surgical means of terminating a pregnancy.

The pill immediately became entangled in international antiabortion politics—including visits to France by both abortion proponents and opponents from the

United States, with the latter threatening boycotts of the manufacturer's other products if the pill were to become available in the US (Ulmann, 2000). Both sides of the abortion debate perceived the stakes surrounding mifepristone to be very high in the US context because of the pill's potential to expand access to abortion. "Performing an abortion" would no longer have to depend on surgical training, and in theory, any clinician with prescription writing privileges could become an abortion provider. Furthermore, abortions could move more easily into settings other than freestanding clinics, and thus bypass the violence that had become so commonplace by the end of the 1980s. As the Feminist Majority enthusiastically (and in retrospect, quite naively) proclaimed on its website (in a statement since withdrawn from the site), once mifepristone was approved by the FDA for use in the US, "the number of abortion providers could double overnight" (The Feminist Majority Foundation, 1996).

During the presidency of George Bush Sr., an import ban was imposed on mifepristone, except for a few research projects. When Bill Clinton came to office in 1993, he lifted the import ban, and furthermore convinced Roussel Uclaf, the French company holding the patent to this drug to transfer US rights to the drug to the Population Council, a non-profit research and advocacy group in New York City (Ulmann, 2000). The Population Council sponsored trials of mifepristone in the US, and additional trials were conducted by a small abortion rights group called Abortion Rights Mobilization (Hilts, 1996).

The FDA gave tentative approval to mifepristone in September 1996, essentially expressing satisfaction with the efficacy and safety of the drug. The remaining steps to approval centered around "manufacturing and labeling issues" (Talbot, 1999). The 4-year gap between "tentative" and "final approval" of this drug offers a very powerful illustration of the thesis of this paper—the difficulties in "normalizing the exceptional". No major pharmaceutical firm stepped forward and sought the commercial rights to offer this drug. Thus, the Population Council, which held the patent, was forced into a series of negotiations, some disastrous, with various would-be manufacturers and distributors (Talbot, 1999). It was commonly understood that the reluctance of regular drug companies to take on this drug stemmed from fears of antiabortion boycotts, and very possibly, violence (Lader, 1995). Finally, the issue of the manufacturer was resolved with the formation of Danco, a small company set up with the sole purpose of producing and marketing mifepristone (Talbot, 1999). The security issues surrounding this enterprise are so great that Danco operates out of an office with an unlisted phone, and with the name of another company on its door.

Yet another problem that delayed final FDA approval was the clash between the agency's traditional expectations of openness with respect to location of the plant where drugs are manufactured, and the need for secrecy on the part of Danco, given the very real threats of antiabortion terrorism (Kaufman, 2000). When the FDA finally did announce approval of the sale of RU-486, it took the unprecedented step of refusing to disclose the name or location of the manufacturer, citing concerns about employee safety and security (Pan, 2000). Thus, we see how the unique politics of abortion—not any inherent questions about the efficacy of the drug—brought a 4-year delay to the drug's approval (and along the way, became one of the defining issues for confirmation of the heads of the FDA during both the Clinton and, currently, the Bush Jr. presidencies).

As noted, final FDA approval of mifepristone occurred in September 2000. That previous June, word had "leaked" to the pro-choice community that the FDA was close to giving final approval of the drug—but with some onerous restrictions (Zimmerman & Lueck, 2000). The most worrisome of these, from an abortion rights perspective, was the stipulation that only those already trained in surgical abortion could offer mifepristone. The ostensible justification for such a restriction was that some 4–5% of mifepristone patients would need surgical backup services, either for a failed abortion, or because of some retained products of conception. This possibility was deeply disconcerting to the abortion rights movement because if the drug were to be made available only to those who already provided surgical abortion, one of the greatest promises of the drug—to bring in new providers—would be negated.

When final FDA approval was announced in September 2000, the above-mentioned restriction was modified to allow non-surgical providers to offer mifepristone as long as they had made back-up arrangements with a surgical provider and would testify to this in writing. The approval also stipulated that the drug could be used up to 49 days of pregnancy, that the provider had to have the ability to "assess the duration of a pregnancy accurately", and to diagnose ectopic pregnancies. Furthermore, in a step highly unusual for the FDA, each physician wishing to use mifepristone had to sign a "provider's agreement" stating that he/she met the above requirements. The provider's agreement also stipulates that he/she will report to Danco all adverse events—"hospitalization, transfusion, or other serious events"—that occur with any patients (Danco Laboratories, 2000a). Equally unusual, each patient that would receive the drug had to sign a detailed "patient agreement", in the physician's presence, consisting of 14 separate points about the protocols of the drug, the patient's certifying her understanding of the length of

her pregnancy and the specific timeframe for returning for care (Danco Laboratories, 2000b). Such FDA-mandated patient agreements are highly unusual, and are typically used in cases of drugs that are acknowledged to be highly dangerous, as with the recent reintroduction of Thalidomide into the US, for the treatment of leprosy (US Food and Drug Administration, 1998). What is unusual in this case is that the FDA had already approved mifepristone as safe some 4 years prior. The FDA issues of concern at this time regarded manufacturing and not drug safety. A final unusual aspect of the agreement worked out between FDA and Danco was that unlike the vast majority of other FDA-approved medications, this drug would not be available in pharmacies via a prescription—but rather each provider would order directly from the manufacturer.

The elation of the abortion rights movement over the long sought FDA approval of mifepristone in Fall (2000) was shortened, a few months later, by the Supreme Court's resolving of the contested presidential election in favor of George W. Bush Jr. During the campaign Bush Jr. had studiously avoided comment on mifepristone, but the pro-choice movement was alarmed when during the confirmation hearings of Tommy Thompson, Bush's nominee to head the Department of Health and Human Services, Thompson stated that he might call for a "review" of the mifepristone approval (Pear, 2001). Since then, the Secretary has backed away from that statement, but almost immediately after the FDA's action, two antiabortion congressmen introduced legislation that would implement the previously proposed FDA restriction confining mifepristone use to surgical abortion providers who are also certified in ultrasound use (S 251/HR482—Patient Health and Safety Act). As of this writing, in Spring, 2002, the fate of this legislation remains unclear.

“Normal” processes of diffusion/adoption of innovation

Once the FDA approves a drug, the process for diffusion into mainstream medical care is strongly influenced by the activities of the drug's manufacturer and the health care system. With regard to the diffusion of mifepristone, the abortion issue complicates each of these routinizing processes.

The estimated cost of discovery or synthesis of a potential new drug molecule is between \$100 and \$500 million (Berkowitz & Katzung, 2001). DiMasi, Hansen, Grabowski, and Lasagna (1991) estimated that the average cost of bringing a new drug to the point of marketing approval was \$231 million in 1987. Although this figure has been recently challenged in a

report from the Public Citizen,⁴ the necessity for high expenditures in order to market a new drug, remains unchallenged. With regard to mifepristone the question is less what it cost to develop the drug—since Danco acquired an already developed product—but rather what it will cost to introduce the drug to physicians. In general, the pharmaceutical industry's marketing efforts are directed at affecting doctors' prescribing habits through six means of drug promotion: detailing, sampling, direct mailing, journal advertising, general media advertising, and the sponsorship of continuing medical education (Schweitzer, 1997). Pharmaceutical sales representatives (“detailers”) have traditionally been an important way of informing physicians about new products, answering questions and maintaining good will. In 1983, more than 55% of US drug company promotional budgets (about \$115 million) was spent on all aspects of detailing (Schweitzer, 1997). This interaction between physicians and detailers often begins in medical school and continues through residency and in practice. The providing of free samples represents another 9% of total promotional expenditures (Schweitzer, 1997). Free samples are especially important for clinics serving low-income patients. A survey by Lichstein, Turner, and O'Brien (1992) found that pharmaceutical companies provided samples in 70% of the resident clinics and 35% of the residents depended on these samples “moderately” or “a lot”. The rationale for the industry in providing samples is that a doctor must be acquainted with the drug in order to prescribe it with confidence. Direct mail claims another 4–6% of the promotional expenditures usually taking the form of free copies of controlled journals and direct advertising flyers from drug companies (Schweitzer, 1997). Medical journal advertising targeted at physicians and public media advertising targeted at patients represent two additional strategies for drug companies. Finally, the sponsoring of continuing medical education (CME) programs is utilized to inform providers of the availability and use for new drugs.

Once a drug has been introduced to physicians, the health care system then usually plays an active role in facilitating or prohibiting uptake. Cost containment is

⁴In 2001, The Public Citizen released a report “Rx R&D Myths: The Case Against the Drug Industry's R&D “Scare Card” challenging the claims that drug development was risky for the pharmaceutical industry (Public Citizen, 2001b). The report argues that the claims for high R&D costs are highly misleading and misunderstood extrapolations from DiMasi's 1991 study. The \$500 million figure which drug companies often cite includes significant expenses that are tax deductible and unrealistic scenarios of risks. According to the Public Citizen Report, a simpler measure suggests that after-tax R&D costs ranged from \$57 million to \$71 million for the average new drug brought to market in the 1990s, including failures (Public Citizen, 2001a).

central to current decision-making by health care systems. Health plans and purchasers often make decisions about promoting the availability of new drugs based on whether it will save money over the alternative options. Cost-effectiveness and cost-benefit studies are usually undertaken to assess the potential of the new drug to reduce health care expenditures. These studies have historically been sponsored by the drug companies themselves, but recently scrutiny over the validity of these results has promoted the conducting of more independent research. Since the early 1990s the federal government has taken an active role in promoting research on both cost and quality of health care through the Agency for Healthcare Research and Quality (AHRQ) formerly the Agency for Health Care Policy and Research, AHCPR), which supports research designed to improve the outcomes and quality of health care, reduce its costs, address patient safety and medical errors, and broaden access to effective services. In addition to conducting cost-related studies, the AHRQ also supports the development of evidence-based practice guidelines.

Possibility of “deskilling” is a third normal factor that facilitates the introduction of a new medication. As drugs are introduced into the health care marketplace that reduce the need for surgical intervention, the level of specialization of the physician is subsequently reduced. Again, concerns about cost containment often prompt the health care system to support the transfer of care management from the level of the specialist to the level of the generalist. For example, under managed care, primary care physicians receive financial incentives to reduce referrals to specialists and to manage patients within their practice. This process is particularly visible in the field of mental health where both pharmaceutical companies and health care systems are expending large resources to train primary care physicians in the medication management of women with depression. In addition to reducing the level of specialty among physicians, the process of medical care deskilling also routinely involves the devolution of care to non-physicians such as nurse practitioners and health educators. This is especially the case when the preponderance of the care involves counseling or education such as diabetes management and weight management.

Lastly the diffusion of the new drug involves the identification of new markets. Drug manufacturers and health care researcher collectively and separately seek to identify additional uses for the medication. As studies are completed, the drug is routinely used “off-label”. This “off-label” use of an approved product for a purpose that is not included in its labeling is common and in accord with FDA guidelines if there is published evidence to support such use (Food and Drug Administration, 1982).

The challenges of implementation

None of these normal processes of diffusion cited above are present in a straightforward manner in the case of mifepristone. First and foremost Danco lacks the financial resources of other pharmaceutical companies since it only makes and distributes mifepristone. As such, it does not have a sales force that can actively engage in detailing nor the funds for large-scale advertising efforts. Sampling is also financially unaffordable for the company since a single packet of three tablets represents an approximately \$600 investment on the part of the company. Also since mifepristone, as noted earlier, must be used in combination with another drug, a prostaglandin (in the United States, the drug misoprostol), the provision of samples of mifepristone is inadequate. Finally, because the drug cannot be dispensed to physicians until they have read and signed the providers’ agreement the provision of samples is even more complicated. Direct mail and medical journal advertising are not without controversy. There is a fine-line between advertising of the drug and what is perceived as the advertisement of abortion, which is viewed by many as inappropriate. Direct-to-consumer advertising has been undertaken by the National Abortion Federation that has received foundation funding to buy advertising space in major women’s journals. This effort has already been challenged in the courts by antiabortion forces (Duin, 2001). Danco has provided funds to support some limited CME activities but they are inadequate to reach a large number of providers and have, to date, been targeted predominately at current providers of surgical abortion.

Rather than visits and gifts from drug representatives and pressure from health care systems to implement cheaper alternatives, the leaders within the pro-choice medical community who are attempting to mainstream this medication, and the on-the-ground physicians who are considering incorporating this medication into their clinical practices, are operating in a unique environment in which the larger politics of abortion constantly hovers above all medical transactions. Put another way, not only are the normal processes of diffusion not readily available, for those who wish to promote this drug, a different—and quite unwelcome—set of factors are present—namely, the scrutiny of antiabortion legislators, lawyers, and activists. In this highly politicized context, the following are some of the challenges to the routinization of this drug within medical practice in the US that we noted in the immediate aftermath of the September 2000 FDA action.

External obstacles

The dosage

One of the first dilemmas to present itself was adherence to the FDA-approved protocol which was

developed by the FDA as a result of the original US trials, run by the Population Council in the mid-1990s. This protocol calls for the administration of 600 mg of mifepristone in the physician office followed by the administration of 400 mcg of misoprostol to be taken orally, in the physician's office, on day three of the procedure. In the years since the original Population Council trials (which ended in 1996) other trials—notably the ARM trials, headquartered at the University of Rochester—had shown essentially the same level of success with only 200 mg of the medication (Ashok, Penney, Flett, & Templeton, 1998; Schaff et al., 1999; Schaff & Fielding, 2000; Schaff, Fielding, Eisinger, Stadalius, & Fuller, 2000a; World Health Organisation Task Force on Post-ovulatory Methods of Fertility Regulation, 2000). Like other health care expenditures, the incentive for both the physician and the payer is to promote the use of the lower dosage. This drug, however, is unlike other drugs and has a preprinted patient agreement that delineates the approved FDA protocol for use. Additionally, unlike other medications, the scrutiny over the provision of abortion caused consternation among many potential providers. Why charge patients for more drugs than they need and why have patients ingest more drugs than they need? Some providers, mindful of the special scrutiny usage of this drug would bring, are hesitant to depart from the original FDA protocol despite the traditional practice of widespread “off-label” use of medications in the field of medicine. Others are engaging in the unusual practice of having the patient sign two consent agreements: the one from Danco and one that indicates that the medication regime to be followed differs from the one indicated in the other signed consent.

In yet another departure from the FDA protocol, many providers also expressed preference for a variation of the administration of misoprostol, the second drug in the mifepristone regime. The original Population Council protocol called for 400 mcg of misoprostol to be taken orally, in the physician's office, on day three of the procedure. The subsequent ARM trials found equal effectiveness with 800 mcg of misoprostol administered vaginally by the patient at home, from 24–72 h after the mifepristone was taken (Schaff et al., 1999; Schaff et al., 2000a; Schaff et al., 2000b; Schaff, Stadalius, Eisinger, & Franks, 1997). This latter protocol is far preferable to many providers because of the inevitable disruptions to office routines—especially the demand on bathrooms—caused by women in the midst of miscarrying. It is obviously preferred by many patients as well who prefer to complete the procedure in the privacy and comfort of their own homes (Elul, Pearlman, Sorhaindo, Simonds, & Westhoff, 2000; Joffe, 1999; Schaff et al., 1999).

The use of this second medication was further politicized when in September 2000 the manufacturer of misoprostol issued a letter explicitly denouncing its

use in medical abortion⁵ (Cullen, 2000). As a response to that letter, ACOG sent a letter to the FDA in October 2000 stating its support for the use of misoprostol in early abortion in combination with mifepristone (ACOG, 2000).

As of Fall (2001), the majority of training and research groups and many individual practitioners appeared to be comfortable with the “evidence-based” usage of 200 mg mifepristone and home-administered 800 mcg vaginal misoprostol (National Abortion Federation, 2001; Stewart et al, 2001), citing the widespread practice of “evidence-based usage” of medications elsewhere in medicine.⁶ But for the more cautious, we can speculate, departure from the original protocol is a worrisome matter, given the highly scrutinized environment in which abortion provision takes place. There remains the unresolved question of legal liability should a patient have a negative health outcome from her use of either medication. Antiabortion opponents have sought to capitalize on the change in abortion regime claiming that providers are implementing the new regime in order to make more money and compromise patient safety (see National Right to Life Committee, 2001b).

Ordering requirements

As mentioned above, unlike most medications approved for use in the United States, under the agreement reach by the FDA and Danco, mifepristone is not to be available in pharmacies, where patients can go with a prescription. Rather, the drug must be ordered directly from the manufacturer by the physician, and both physician and patient must sign agreements pertaining to its use. For those already established in abortion services—i.e. freestanding clinics or individual physician offices that offered surgical abortions—this has not proved overly burdensome. But for potential new providers of abortion services, for example, faculty in hospital-based residency programs, negotiating the intricacies of this requirement with hospital-based pharmacies can be frustrating and time consuming.

⁵ Misoprostol, most commonly known under the trade name, Cytocec, received initial FDA approval some time ago as an ulcer drug, but besides its “off-label” use in medical abortion, it has also been widely used in a range of obstetrical practices, which helps account for ACOG's prompt response to the Searle action. G.D. Searle and Company was the pharmaceutical unit of Monsanto company which joined with Pharmacia and Upjohn on April 3, 2000 to create the Pharmacia Corporation (Pharmacia Corporation, 2001). Since the dissemination of the “Searle letter”, Pharmacia Corporation has made no further attempts to limit access to misoprostol.

⁶ Where there is substantial research and scientific evidence to support a particular “off label” use of a medication, the term “evidence-based” is used to designate the regimen.

Likewise, because many health care systems are engaged in large-scale drug purchasing arrangements, physicians within these systems may not have the ability to order medications directly from Danco, as is required. And this unusual requirement can also be off-putting for private practice physicians contemplating merely a handful of medical abortions a year, and reluctant to purchase the drug in advance, and “to have that stuff just expiring in your closet”, as one medical physician activist speculated to us. It is still too early to tell whether this unusual ordering procedure will in itself be a widespread disincentive for the use of mifepristone.

Use of ultrasound

Whether or not to use ultrasound is a third perplexing issue as the first generation of mifepristone users get underway. In fact, nearly all of the veteran surgical providers who are incorporating this drug into their practices do routinely use ultrasound—as by now, most routinely use this in surgical abortion (Joffe, 1999). The question is, “Is it necessary?” This question is possibly quite relevant for the spread of this regime to new providers. Family practice physicians, for example, who are seen as among the biggest potential ‘new’ providers, very often do not own such machines—which can cost from about approximately \$12,000 to almost \$100,000 depending on the model. Among the first generation of mifepristone “pioneers”, i.e. those who participated in the US trials and helped establish the first protocols for various pro-choice medical groups, there was lively debate on this topic, and the decision was ultimately made to recommend, but not require, use of ultrasound (National Abortion Federation, 2001; Stewart et al., 2001). The FDA approval in September 2000 did not require use of ultrasound. Those arguing against the absolute requirement of ultrasound pointed to the fact that in France, where mifepristone was developed and first used, this technology is not routinely used, and that other reliable methods—most notably, a pelvic exam and a patient’s medical history—exist for reliable dating of early pregnancies (Ellertson et al., 2000). Serial β HCG blood tests can be used in exchange for ultrasounds to follow potential medication failures or ectopic pregnancies.

To be sure, various arrangements are available to potential mifepristone users in differing situations. Those in a group practice may be able to send a patient for an ultrasound to a colleague who does have this technology. Various efforts are underway by pro-choice medical groups, such as National Abortion Federation and Planned Parenthood, to expand training in ultrasound for potential providers of mifepristone. Group purchasing agreements will be increasingly available and the price of ultrasounds is expected to reduce over time. Nevertheless, for some potential providers, the perception that ultrasound should be routinely used for

medical abortion may be a disincentive to proceed, if this technology is not readily available. Again, we can point to the special scrutiny that abortion care typically receives to understand provider reluctance to depart from commonly used protocols, even if not formally required.

Insurance reimbursement and malpractice coverage

Resolving issues of insurance reimbursement and malpractice coverage are among the most consequential aspects of the normalization of mifepristone into medical circles. Very gradually in early 2001, commercial insurance companies began to establish guidelines in this area. Most commercial insurers announced they would treat medical abortion similar to surgical abortion. Thus, for those individuals or facilities already offering surgical abortion, reimbursement has not been that problematic. For new providers, however, the situation was more problematic, and often involved negotiating new terrains they had not previously entered (Joffe, 2000).

Medicaid, in state programs that reimbursed for surgical abortion, has also begun slowly to issue guidelines. This has in some cases proved extremely difficult, as the stringent policies established for surgical abortion often did not make sense for the medical abortion regime, for example, requirements governing width of aisles, number of sinks in the operating suite and so on.

The issue of malpractice coverage for new providers remains at this point an even more challenging issue. Those contemplating adding mifepristone to their services, especially in a private or group practice situation, typically face considerably higher malpractice rates. (The situation is usually much easier for those who work in hospital-based clinics or community-based clinics, and thus are covered under the institutions’ policies—unless of course, such policies specifically prohibit abortion coverage, as is the case in some publically funded facilities). In the long run, the most likely solution to this problem may be group malpractice policies worked out by such organizations as the National Abortion Federation or other pro-choice medical advocacy groups. In the short run, however, malpractice may prove a significant stumbling block to commencing mifepristone provision on the part of those who are otherwise prepared to do so.

Legal issues

Similarly, it is of enormous consequence as to how the legal issues that presently govern surgical abortion in various states will be applied to medical abortion. Among the most outstanding of these issues: parental notification and consent laws; 24–48 h waiting periods; reporting requirements; physician only laws; and laws governing treatment of fetal tissue.

Generally speaking, legal experts have concluded that “medical abortion will...be regulated in much the same way as surgical abortion”, especially with respect to parental involvement and mandated waiting periods (Borgmann & Jones, 2000). However, in a number of specific cases of legal regulations, the quite different nature of the two abortion modalities may give medical abortion providers grounds for successful appeal of these laws. For example, so-called TRAP laws (“targeted regulations of abortion providers”) exist in a number of states and consist of detailed, often burdensome requirements covering, among other things, the physical facilities in which abortions may take place, regardless of the nature of the abortion procedure. As the authors of a key statement on legal aspects of medical abortion put it, “these restrictions...are particularly irrational when applied to medical abortion...it is non-sensical to require recovery rooms with 4 beds or a minimum square footage for operating room” (Borgmann & Jones, 2000). Similarly, some state laws governing fetal tissue examination are notoriously difficult to implement—if not absurd—when applied to medical abortion; some states’ laws, for example, require physician examination of fetal tissue. While comprehensible for surgical abortions, in the case of medical abortion, such laws would either require that patients’ remain in the facility to expel the tissue, or, after expelling the tissue at home, i.e. undergoing the induced miscarriage, bring back the tissue to their doctors’ offices (Kolata, 2000).

Finally, “physician only laws” which now apply in most states (only in Montana, Vermont and New York, do non-physicians now provide surgical abortions) may also have different implications for medical abortion. Given that medical abortions involve a discrete sequence of steps—none of which involve surgery—many have noted that this modality may be especially suited to involvement of non-physicians, and in some locales, perhaps amenable to legal challenge. However, all these legal issues currently remain unclarified and hence, new providers must proceed as if they were still in effect (Borgmann & Jones, 2000). The net effect therefore of these myriad laws is that new providers, perhaps contemplating only a handful of mifepristone abortions per year, must become conversant with a legal apparatus unlike no other in contemporary medicine.

Internal issues

“Turf issues”

Accompanying the unique external challenges facing the adoption of mifepristone are some of the familiar “turf” issues of medicine, which are a factor here as elsewhere in the profession. For example, while abortion provision historically has been most tied to the specialty

of obstetrics and gynecology, some family practice physicians and other generalists have long been involved in surgical abortion. And in spite of the well-documented shortage of abortion providers, some voices within obstetrics and gynecology have been resistant to the involvement of others. Mifepristone, moreover, as already noted, dramatically increases the potential for the involvement of not only non-obstetrician/gynecologists, but advanced practice clinicians or “midlevel providers” as well (Clinicians for Choice, 1996; Kaiser Family Foundation, 1997; National Abortion Federation, 1991). Furthermore, this potential for new providers is occurring simultaneously with the pronounced drop in the number of abortions overall in the US that began in the mid-1990s and continues through to the present (Henshaw, 1998). Though no concrete data is available on the implications of all these factors, one can speculate that this may have complicating effects, for example, competition between obstetrician/gynecologists and family practice residencies for the dwindling number of abortion patients if both departments within a hospital decide to do resident training in medical abortion, or conceivably, a reluctance of obstetrician/gynecologists to serve as surgical back-up for family practitioners in some cases, as anecdotal reports reaching us have suggested.

Fear of adverse events/“cowboys”

In all areas of medicine, practitioners have some trepidation of the “cowboys” among them—i.e. those who are oriented toward practicing medicine “recklessly”, or who at least depart in significant ways from the protocols of most of their peers. Given the excellent safety record of abortion provision in the US (Council on Scientific Affairs American Medical Association, 1992), there is no reason to assume that the abortion field has more “cowboys” than other branches of medicine. Indeed, given that first-trimester abortion has been shown to be 10 times safer than childbirth (Hakim-Elahi, Tovell, & Burnhill, 1990), arguably this field attracts less incompetent providers. However, given the intense scrutiny that abortion provision receives, fear of the damage that could be done by an inept practitioner is especially strong. Indeed, although the Institute of Medicine recently estimated that between 44,000 and 98,000 Americans die each year as a result of medical errors (Kohn, Corrigan, & Donaldson, 2000), it is not lost on the abortion providing community that abortion-related deaths receive disproportionate attention and far more severe penalties than other categories of physicians—as testified by the recent conviction on manslaughter charges and the prison term of a California abortion provider whose patient died after a

missed perforation,⁷ rather than the more typical civil penalties that are common elsewhere when medical mistakes occur.

Throughout the process leading up to FDA approval and continuing through to the present, antiabortionists have relentlessly campaigned about the alleged medical dangers of mifepristone (Boonstra, 2001; National Right to Life Committee, 2001a; Seckora, 2001). Some of these allegations pertain to the supposed properties of the drug itself—“chemical warfare attack on unborn Americans”, as one group claims (Jasper, 2000); “mifepristone may cause breast cancer” was posted on another antiabortion website (Coalition on Abortion/Breast Cancer, 2001). Such claims are easily dismissible—in fact, mifepristone has long intrigued scientists for its potential to *cure* certain forms of breast cancers. (The drug has already shown potential to treat some forms of other cancers, such as meningiomas, and “compassionate use trials” are underway for the latter. Feminist Majority, 2001). But other antiabortion critiques directly address the dangers of inappropriate patient management—i.e. that the patient could suffer serious injuries or even die of excessive bleeding if not monitored properly by the doctor administering the mifepristone. Hence, the specter of an inept or reckless practitioner is particularly worrisome for this movement. In short, as in all other fields of medicine, innovators in this field are anxious for competent physicians to take up this new modality—and for incompetent ones to avoid it. The crucial difference here between abortion providers and others is, as the logic of this paper suggests, that the stakes for the former are so much higher when mistakes are made.

In the approximately 6000 patients who had mifepristone abortions in the two US trials, no serious injuries or complications were reported; a few patients needed blood transfusions after the mifepristone regime. Since general distribution in the US starting in September 2000, there have been a handful of adverse events. There have been three reports of women who

took mifepristone despite having ectopic pregnancies, with one resulting in a fatality; there has been one reported case of a serious and rare bacterial infection in a mifepristone patient (with an additional infection occurring in a mifepristone patient in Canada, which resulted in a fatality); and a report of a heart attack of a woman in her twenties, three days after completing the mifepristone–misoprostol regime. These events prompted the FDA to work with Danco, in April 2002, to issue a “Dear Dr.” letter, which was sent to all those who had ordered mifepristone from the manufacturer. The letter reaffirmed the importance of ruling out ectopic pregnancies prior to mifepristone administration (as the drug is not effective in such cases), as well as the prescribing physician’s obligation to inform the FDA of all such adverse events. The letter also stipulated that “no causal relationship has been established between the drug and the illnesses in any of the cases” (Okie, 2002).

There has been no suggestion, in any of the cases discussed in this letter, of any provider recklessness or incompetency. Following the release of the letter, the response of the antiabortion community to these events appeared to be slight. However, it is virtually certain that the antiabortion community will eventually attempt to use these and other reported serious complications for political gain. What makes the potential defense of mifepristone by the pro-choice community particularly complex is the lack of an adequate database of all patient outcomes. Although numbers for the trial participants have been carefully monitored, there is no reliable way of knowing how many mifepristone abortions are currently taking place in the US, now that the drug is available for general use, and by what kinds of practitioners. In contrast to other pharmaceutical companies that seek to disseminate information on usage and provider preference for their medications, Danco has guaranteed the absolute confidentiality of all providers using or inquiry about mifepristone. Thus, as these and future adverse events come to be debated, there will be an insufficient larger context in for defenders of mifepristone in which to place such an event.

Fear of non-compliant patients

Finally, mifepristone abortions involve unique issues of patient “compliance” that are typically not an issue with surgical abortions. While the latter can typically be completed in one patient visit, the former involves two, and sometimes three office visits: the patient is given the mifepristone at the first visit; then, depending on which regime for misoprostol the provider uses, the patient is either told to return to the office for misoprostol insertion or given the second drug to be inserted at home; all patients are required to return for a final visit to ascertain that the procedure has been completed. Furthermore, the mifepristone regime involves more

⁷In 1996, the Riverside County, California District Attorney arrested and charged Dr. Bruce Steir, an abortion provider, with second-degree murder of a woman who underwent a second-trimester abortion and died several hours later from complications of a perforated uterus. Dr. Steir was forced to turn over his license, and in 2000, Dr. Steir accepted a plea bargain of involuntary manslaughter serving 6 months on a 1-year jail sentence (Reproductive Freedom Task Force, 2000). On February 1, 2001, Dr. James Pendergraft, a high-profile African-American abortion provider, was convicted of Federal extortion in Ocala Florida, and sentenced to 46 months in Federal prison, 2 years probation upon his release, and \$25,000 fine (Reproductive Freedom Task Force, 2001). Advocates argue that these two cases represent a new front of attacks on abortion providers, that of politically motivated criminal prosecutions (Reproductive Freedom Task Force, 2001).

patient counseling, including extensive instructions on when a phone call back to the office is warranted, especially in cases of excessive bleeding.

Mifepristone abortions, in short, involve health care providers having to cede some degree of control to their patients, an already difficult issue for some health professionals, and one made even more complex, as this paper argues, by the high degree of scrutiny that is always present in abortion. Thus, early research on surgical abortion providers who began to incorporate mifepristone into their practices showed some ambivalence about this loss of control, and fears about patients who would not comply with the more complex regimes associated with the new procedure (Simonds, Ellertson, Winikoff, & Springer, 2001; Joffe, 1999).

Conclusions: sociological implications

Speculating about the future of mifepristone in the US, probably the most likely scenario in the immediate future is a steady and continuing adoption of the drug by surgical providers. The use of this drug by “new” providers will, for the various reasons cited above, probably be quite gradual. Abortion rights supporters can be cautiously optimistic about more non-surgical providers offering mifepristone in the future, as more and more reports of successful use reach the medical literature, as the cumulative effects of various training initiatives underway by pro-choice medical organizations take hold, and most significantly, if American women become educated about this drug and ask their primary care providers to provide it. Such a slow but steady scenario, of course, depends on a fairly stable political environment surrounding abortion. Should changes in the Supreme Court lead to a repeal of *Roe v Wade*, or should even the present Court follow the lead of antiabortionists in seeking to establish the legal personhood of the “unborn”, as several judicial and legislative overtures are now seeking to accomplish⁸ or should violence against abortion providers escalate and go unchecked in the Justice department, the promise of mifepristone could be stalled indefinitely. And, as already suggested, should a high profile “adverse event” occur, this could spur the FDA or Congress to impose more stringent restrictions on who can prescribe mifepristone. Even without these political scenarios, though, our argument in this paper is that at almost every level, the adaptation of a quite simple medical

regime is rendered more cumbersome by the unique circumstances surrounding abortion.

The still unfolding story of the coming of mifepristone to the United States carries several intriguing sociological implications. First, this saga casts strong doubt on the inevitability of “technological determinism” within medicine (Atkinson, 1995; Banta & Luce, 1993; McKinlay & Hafferty, 1993; Novaes, 2000; Turner & Samson, 1995)—at least when such a socially controversial medical procedure is involved. The fact is that a new and proven effective technological innovation became available for one of the most commonly sought medical procedures in the US—some 43% of American women, according to the Alan Guttmacher Institute, will have at least one abortion by the time they are 45 years old (AGI, 2000). This innovation, moreover, could potentially eliminate the need for surgery for many of the abortions now taking place within the United States (for example, the approximately 50% of abortions that occur within the first 7 weeks of pregnancy). Yet these features did not smoothly translate into the widespread adoption of this technique. Nor is this likely to change quickly in the future.

Rather, the various challenges noted in this paper to routinize the use of mifepristone give further confirmation to the extraordinary degree to which the medical nature of abortion provision has been overwhelmed by larger abortion politics. Certainly, the mifepristone story in the US to date gives powerful support to Latour’s observation that “science is politics by other means” (Latour, 1988); see also Clarke & Montini, 1993).

But the mifepristone struggle in the U.S is far from over. We use the word “struggle” advisedly. Although physicians and other health care workers are most often spoken about sociologically using the language of the sociology of professions (Freidson, 1970a, 1970b) and although certain concepts from this tradition are undeniably relevant here (for example, the turf wars between specialties), we believe the field of social movements offers another quite useful frame in which to understand the mifepristone story to date, and to speculate about the future. Though social movement activism with regard to health care and medicine is typically conceptualized within sociology in terms of lay mobilization against professional dominance and authority (Epstein, 1996; Ruzek, Clarke, & Olesen, 1997) there is also a nascent tradition of scholarship at the interface of social movements and health care research which focuses on medical personnel themselves as social movement activists (Hoffman, 1989; Lo, M., 2002).

Social movements, as we know, create “counter movements” (Lo, C., 1982)—and just as the 1973 *Roe v Wade* decision created the modern “prolife” movement (Luker, 1984), so the excesses of the latter helped create and sustain activist wings within the traditionally

⁸Efforts to extend fetal personhood are occurring at the federal and state levels. These efforts are reflected in the passage of the “Unborn Victims of Violence Act” in 2001 (Michelman, 2001), and in the construction of bans on so-called “partial-birth abortions” (Center for Reproductive Law and Policy, 1998).

apolitical medical profession, as demonstrated by the founding of Medical Students for Choice after the first killing of an abortion provider in 1993 (Joffe, Anderson, & Steinauer, 1998). Thus, when speculating about the future of mifepristone in the US, we can anticipate more and more engagement by pro-choice health care providers in various “political” activities traditionally associated with social movements (and thus, historically labeled as “unprofessional” by many of their medical colleagues).

In this vein, this paper concludes with an observation on the quite different political environments after two crucial developments in abortion policy in the US: the *Roe v. Wade* decision in 1973, and the FDA approval of mifepristone in 2000. After the first—itsself achieved by both a politicized wing of the medical community and feminist activists (Joffe, 1995; Luker, 1984; Petchesky, 1984)—the political momentum was seized, as mentioned above, by a newly created “prolife movement”. The pro-choice forces within medicine and feminism relaxed their vigilance, and the mainstream medical establishment, though on record as approving of legal abortion, maintained a distance from abortion, and the immediate post-*Roe* period was noteworthy for what did *not* happen in medicine—i.e. most hospitals did not establish abortion clinics, residencies for the most part did not establish training programs, medical organizations (with the notable exception for the American Public Health Association) did not establish standards for abortion care and so on (Joffe, 1995).

The situation, in the aftermath of the FDA action of September 2000, is a quite different one. In large part because of the battles fought over the 27 years since *Roe*, there are now several highly organized abortion rights groups within organized medicine—the National Abortion Federation, Physicians for Reproductive Choice and Health, Medical Students for Choice, pro-choice blocs within the American Medical Women’s Association, and within such specialty groups as the Society for Teachers of Family Medicine and ACOG. These groups have been proactive at every stage of the coming of mifepristone to the U.S: testifying before the FDA, promulgating standards of care, speaking to the media, and perhaps most importantly, as noted above, in offering training to health care providers in a variety of settings about the use of mifepristone. Besides such formal activities, these physicians committed to furthering the adoption of mifepristone work tirelessly on a more informal level to facilitate mifepristone use among medical colleagues: for example, they help novice users maneuver the intricacies of ordering the drug, advise on insurance reimbursement and malpractice options, and make themselves available to new users to offer support about any issues that emerge. These pro-choice physicians also undertake advocacy work within medical bureaucracies—for example, by lobbying sympathetic

but wary residency directors in obstetrics and gynecology and family practice programs to allow training in medical abortion, or by advocating the inclusion of sessions on medical abortion on the conference programs of professional associations, such as ACOG and the American Academy of Family Practice.

This is hardly to suggest that such activities, in and of themselves, can completely compensate for the difficulties, discussed throughout this paper, in “routinizing” mifepristone within US medicine. Indeed, the very reluctance of otherwise sympathetic health care professionals to appear “too political” may impede the ability of this new drug to attract new abortion providers. But the range of efforts now underway to mainstream mifepristone makes amply clear that in the quite exceptional case of abortion, those physicians who are currently trying to promote this new abortion regime can most fruitfully be understood, from a sociological perspective, as political activists as well as health care professionals. How these proponents negotiate these two identities—historically seen as at odds with each other—will be an important determinant of the fate of mifepristone in the United States.

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