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Commentary

Mifepristone label laws and trends in use: recent experiences in four US states

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In the 15 years since approval of mifepristone in the United States, there have been numerous changes in the political, legal and medical contexts surrounding abortion provision. Not surprisingly, use of this simple technology has risen fairly steadily over time, from just 6% of all eligible abortions in 2001 [1,2] to 29% in 2011 [3]. Research on women's abortion-related preferences as well as experience from other countries suggests that use of mifepristone relative to all abortions might be considerably higher than 29% if unconstrained access to medical abortion were the norm, rather than the exception [4–8].

Perhaps as a result of its rise in use over time, or maybe in recognition of its revolutionary potential, antiabortion activists have recently turned their attention to promotion of mifepristone-specific legislation. Two common types of mifepristone restrictions target providers and clinics in an effort to reduce service availability. "Physician only" laws, which now exist in 38 states, limit provision of medical abortion to licensed physicians despite broad recognition that midlevel providers can also safely administer this medication [9]. "Physician presence" laws, which now exist in 16 states, require that the prescribing physician be in the physical presence of the patient, thus preventing use of telemedicine for medical abortion provision [9]. Supply-side policies such as these have been recognized as being more effective than demand-side policies that target women in an effort to diminish use of services [10].

A third type of mifepristone restriction is more complicated than its supply side counterparts. "Food and Drug Administration (FDA) protocol" laws are essentially a hybrid strategy that aims simultaneously to reduce abortion supply and demand through targeting all affected parties: clinics, providers and women. Such laws, now in effect in three US states (North Dakota, Ohio and Texas), require that mifepristone be provided in accordance with the FDA-approved label. This involves use of an outdated regimen of 600 mg that is more expensive and arguably less effective, with greater side effects than the evidence-based regimen of 200 mg that is the current standard of care worldwide [11]. The FDA label also requires additional clinic visits and limits use of the drug to 49 days LMP or less rather than 63 days or less, which has been the routine upper limit for this regimen in clinical practice [12] and has been proven to be safe and effective [11].

This hybrid strategy appears to be working. A recent analysis of the effect of the omnibus antiabortion legislation in Texas that was enacted in 2013 and included a mifepristone-label restriction found that within 6 months of enactment, the share of all eligible abortions statewide that were medical declined by 70% when comparing the 6-month period directly prior to passage of the bill with the 6-month period directly after its passage [13]. Notably, there was just a 13% decline in overall abortion incidence during this same period. In addition, the number of abortion facilities statewide decreased by nearly one-half.

In order to examine further the possible effect of mifepristone-specific restrictions, we documented trends in mifepristone use over a 10-year period (2004–2014) in four large US states: California, New York, Ohio and Texas. We

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selected these states because they each have large populations of reproductive age women and because they fall on opposite ends of the abortion restriction spectrum: California and New York are two of the least restricted states in the country with no mifepristone-specific restrictions, while Ohio and Texas are two of the most restricted states, each with mifepristone label laws that went into effect in February 2011 and November 2013, respectively. In addition, we documented trends in mifepristone use relative to the number of all abortions in New York and Ohio from 2004 to 2013. California and Texas were excluded from this analysis due to incomplete abortion incidence data for some or all of the 9-year period. The data for these analyses were obtained from the US distributor of mifepristone and from the state health departments of New York and Ohio [14].

Fig. 1 shows the annual percentage change in mifepristone use within each state compared with baseline use in 2004. In California and New York, there were steady increases for most of the 10-year period. In Texas, mifepristone use increased substantially through 2012 and then began to decline sharply in 2013, the year the omnibus abortion bill went into effect. In Ohio, mifepristone use was relatively stable through 2010, followed by a steep decline in 2011 that coincided with enactment of the FDA protocol law. Mifepristone use has remained relatively flat since 2011 at a level that is about 75% lower than in 2004. Fig. 2 summarizes annual mifepristone use relative to the total number of abortions in New York and Ohio from 2004 to 2013. In New York, the proportion of all abortions that are medical has been rising steadily since 2006. In Ohio there was a similar pattern until 2011, when mifepristone use declined sharply. Since then, medical abortions have comprised less than 2% of all abortions statewide.

The stark divergence in recent mifepristone trends can also be clearly seen in Table 1, which summarizes the percentage change in overall abortion procedures and in medical procedures in New York and Ohio between 2004 and 2013. In both states, the number of abortion procedures during this period declined, reflecting the larger national trend [15], yet the scale of decline in Ohio was double that in New York. In contrast, there were marked differences in both the direction and the magnitude of changes in mifepristone use. In Ohio, the decline in mifepristone use was nearly five times greater than for all abortions, whereas in New York, mifepristone use increased despite an overall decline in all abortions during this same period.

These findings indicate that mifepristone restrictions are having a rapid and detrimental effect on medical abortion use in Ohio and Texas. This can be seen in both the timing and scale of the declines, which in both cases coincided with initial enforcement of the FDA protocol laws, as well as in the stark contrast in mifepristone use over time in these four states on opposite ends of the abortion restriction spectrum. In light of this, it appears that many women in Ohio and Texas who might have selected medical abortion under less restricted and burdensome circumstances are increasingly resorting to surgical abortion. Those who opt for mifepristone in spite of the onerous restrictions are receiving substandard care with the explicit approval of their state governments. The consequences of this are still not well known but are almost certainly not trivial. For example, a recent study of the effect of the FDA protocol law in Ohio found that use of the outdated mifepristone regimen is associated with a significant increase in the need for additional intervention, most often another dose of misoprostol or aspiration [16].

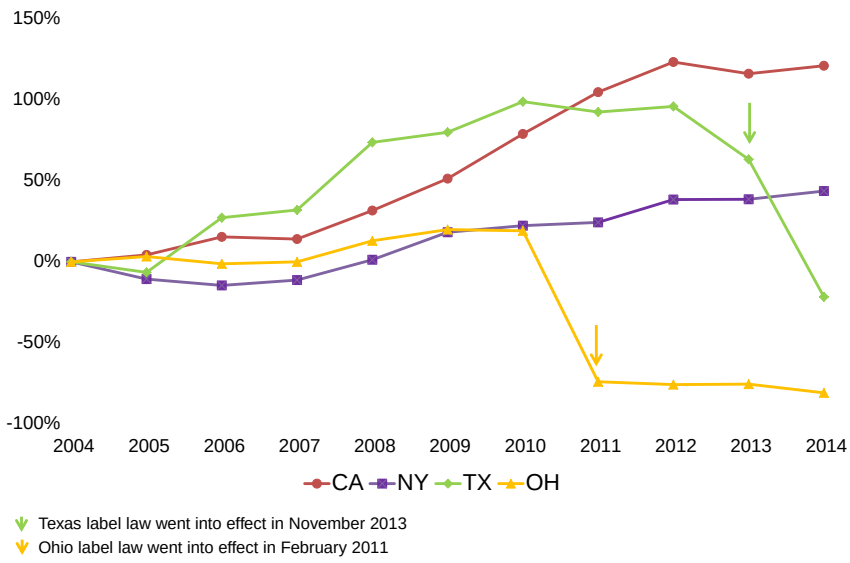

Fig. 1. Changes in mifepristone use in four states relative to use in 2004.

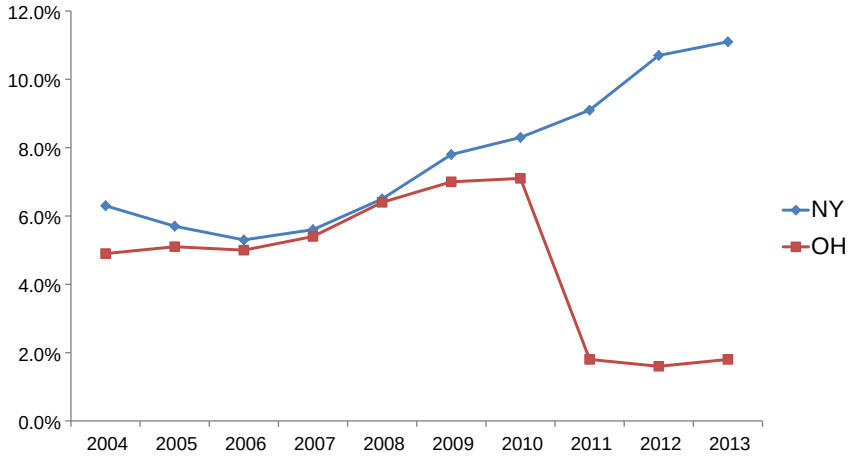

Fig. 2. Annual mifepristone use relative to all abortions in New York and Ohio: 2004–2013.

Fortunately, efforts are underway to update the FDA label, which could immediately confound the protocol laws in all states in which they have been enacted. Nevertheless, the fact that these restrictions were ever approved in the first place raises important questions about the role of state governments in regulating medicine. The practice of prescribing drug regimens that vary from approved labeling is lawful, common and frequently accepted as the standard of care [17,18]. This is all true in the case of mifepristone, for which there is considerable evidence on the safety and efficacy of the lower dose [11]. In light of this, state laws that require adherence to the original FDA-approved protocol are not in the interest of any relevant parties involved in this medical procedure. It is not in the interest of the commercial entity selling the drug or the physicians who are being required to provide substandard care to patients, or the standalone abortion clinics that are losing income and clients, and most importantly, it is not in the interest of women — approximately one-third of whom will need abortion services at some point in their reproductive lives [19].

Even after 15 years of availability in the United States, the promise of mifepristone has yet to reach its full potential. In order to ensure that all American women who want and need medical abortion are able to receive it, the states must no longer be allowed to mandate inferior medical practice.

Table 1
Change in abortions and medical abortions in Ohio and New York: 2004–2013.

	All abortions	Medical abortions
Ohio	−17%	−79%
New York	−8%	+13%

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