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Contents lists available at ScienceDirect

Contraception: X

journal homepage: https://www.journals.elsevier.com/conx





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ARTICLE INFO

Article history:
Received 16 June 2020
Received in revised form 25 September 2020
Accepted 3 October 2020
Available online xxxx

Keywords: Abortion Abortion provision Medication abortion Mifepristone First trimester

ABSTRACT

Objective: The objective was to examine trends in the number of low-volume and nonmetropolitan mifepristone purchasers and their role in the expansion of medication abortion.

Methods: We use deidentified data from Danco Laboratories, the sole distributor of mifepristone during the study period, to examine trends in mifepristone distribution. We focus on customers who purchased <100 doses a year and a subset of those who purchased <10 doses for the periods of 2008–2011 and 2014–2017. We use data from the Guttmacher Institute Abortion Provider Census (APC) studies in 2008 and 2017 to examine the extent to which some facilities that purchased mifepristone may be missing from Guttmacher's APC.

Results: Between 2008 and 2017, the number of medication abortions increased 73%, though the number of mifepristone purchasers only increased 15%. The number of low-volume mifepristone customers, or those who purchased <100 tablets of mifepristone per year, decreased 8% over the study period, while the number purchasing <10 tablets per year decreased 14%. However, in recent years, low-volume customers were more likely to have purchased mifepristone in multiple years. In nonmetropolitan areas, the number of sites purchasing mifepristone increased slightly but the amount of mifepristone that was purchased more than doubled between 2008 and 2017.

Conclusions: While reliance on medication abortion increased substantially between 2008 and 2017, there is no evidence that this was due to an increase in the number of facilities that purchased low volumes of mifepristone. *Implications:* While their numbers declined, abortion providers purchasing low volumes of mifepristone likely played an important role for the individuals they cared for. Access to abortion could increase if a wider network of health care practitioners, especially those in settings that do not currently provide abortions, was able to offer medication abortion.

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1. Introduction

When mifepristone was approved by the FDA in 2000, many expected that medication abortion would be adopted by health care providers in private practice and other settings that did not previously provide abortions [1]. This would have reduced the concentration of abortion care in specialized clinics and, in turn, reduced abortion stigma. Mifepristone also had the potential to expand abortion access to communities where there were no procedural abortion providers, including smaller metropolitan and rural areas [2,3].

Mifepristone has changed the face of abortion care in the United States but not necessarily in the ways originally anticipated. In 2017, there were 339,640 medication abortions (39% of all abortions), and the overwhelming majority of clinic facilities providing abortions (97%) offered mifepristone [4]. At the same time, data from the Guttmacher Institute's Abortion Provider Census (APC) studies suggest that the number of physicians' offices known to provide abortion care declined 32% between 2000 and 2017 [4,5]. However, a complementary

study by the Guttmacher Institute also found that their 2014 study may have missed as many as 1500 obstetrician-gynecologists providing abortions in private practice settings [6]. Thus, it is possible that the APC studies do not capture low-volume abortion providers.

Using deidentified data from the US distributor of mifepristone, this study examines trends in low-volume mifepristone purchasers — those likely to be operating in settings other than abortion clinics — to determine if numbers increased between 2008 and 2017. Additionally, we examine changes in mifepristone purchasers in nonmetropolitan areas to determine if volume of mifepristone purchased increased in areas that may have reduced access to abortion care.

2. Methods

2.1. Data sources

Data on mifepristone distribution come from Danco Laboratories, the only distributor of mifepristone in the United States during the study period. The data consist of monthly sales for the years 2008–2011 and 2014–2017. (The original file contained information for 2012 and 2013. However, some customer identification numbers were changed

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due to a software update in 2013, and some of the revised customer identification numbers could not be linked after this year. Focusing on 2008–2011 and 2014–2017 allowed us to examine continuity in sales based on consistent customer identification numbers.) The file did not include any identifying information such as names or addresses but did include the zip code for the location where the drug was mailed to. The files did not contain any information about facility type (e.g., hospital, private practice) or provider specialty (e.g., obstetriciangynecologist, family physician).

Several assumptions inform our interpretation of the Danco data. The original FDA-approved regimen entailed a 600-mg dose of mifepristone or 3 mifepristone pills [7]. Even before the FDA approved mifepristone, evidence-based regimens involving 200 mg of mifepristone (1 pill) were found to have similar efficacy [8,9]. As early as 2001, more than 83% of abortion providers were using the 200-mg regimen [5]. On March 29, 2016, the FDA updated their regimen to align with standard medical practice, changing the dose to a single 200-mg pill [7]. Until October 2016, mifepristone was sold in packets of 3, and our analysis assumes that each 3-pill packet represents 3 abortions. During part of the study period, North Dakota, Ohio and Texas enacted laws requiring that medication abortion be provided according to the original FDA 3-pill protocol [7]. We adjusted sales in these states during the relevant periods and assumed that 3 doses represented 1 abortion in these cases.

Our analysis assumes that mifepristone was used only for abortion. While recent research has shown that it can be used for miscarriage management [10], there is no documentation to suggest that it was widely used for this purpose during the study period. The estimated number of medication abortions per year generated using Danco data aligned (98%–100%) with the number of medication abortions reported by the Guttmacher Institute in relevant years [4,11], indicating that most mifepristone was used for medication abortions.

The analysis also uses data from the Guttmacher Institute's APC studies for the year 2008 and 2017 [4,12] to examine geographical areas where purchasers of mifepristone were not captured by the Guttmacher studies. Guttmacher proactively contacts all health care facilities known to have provided abortion care during the relevant survey period and collects information about the number of abortions provided as well as other aspects of service delivery. It is considered to be the most accurate source of data on abortion incidence and number of health care facilities providing abortion in the United States [13]. More information about the data collection efforts and procedures is available elsewhere [4,12].

This study does not rely on data obtained from human subjects and was deemed exempt from review by the Guttmacher Institute's federally registered Institutional Review Board.

2.2. Measures and definitions

We measure the quantity of mifepristone purchased each calendar year. This analysis focuses on two categories of low-volume mifepristone purchasers: those who purchased <100 pills per year (low volume) and the subset who purchased <10 pills per year (lowest volume). These low-volume purchasers may have provided mifepristone to a substantial number of patients but were unlikely to be primarily identified as abortion providers. The median number of abortions (procedural and medication) provided by clinic facilities (both abortion clinics and nonspecialized clinics) was 861 in 2008 [14] and 568 in 2017 [4]. In contrast, obstetrician-gynecologists providing abortions in private practice settings reported a median of 10 abortions per year, some of which were procedural [6].

For each 4-year time period, we examine the number of years lowand lowest-volume providers purchased mifepristone. For these analyses, we exclude providers who only purchased mifepristone in 2011 or 2017, as these were potential first-time customers who went on to purchase in subsequent years. This practice provides a better understanding of the extent to which low- and lowest-volume facilities provided medication abortions regularly, or at least for more than 1 year. Using zip code data, we also examine low- and lowest-volume providers located in nonmetropolitan areas, distinguishing micropolitan from rural areas. The US Census Bureau defines micropolitan areas as small urban areas with at least 10,000 residents but less than 50,000. For purposes of this analysis, we designate rural areas as all remaining geographic areas that are neither metropolitan nor micropolitan.

2.3. Analytic strategy

Using Danco sales data, we first examine trends in the number of medication abortions and total number of active Danco customers, including low- and lowest-volume purchasers, for the periods of 2008–2011 and 2014–2017. We next examine the extent to which facilities that only ever purchased $<\!100$ and $<\!10$ doses of mifepristone per year did so in multiple years — nationally and by type of nonmetropolitan area.

It is possible that health care providers who did not previously provide abortions have become increasingly familiar with mifepristone and have started offering medication abortion. In turn, we anticipated that the number of medication abortion providers not captured in the Guttmacher Institute APC surveys would increase over the study period. To assess this, we examine the number of low-volume Danco mifepristone purchasers located > 10 and > 50 miles from abortion providers captured in the Guttmacher Institute APC. We used street addresses to generate geo coordinates for the abortion providers in the APC. We used the Stata function *geonear* to estimate Euclidean distance from the centroid of the zip code where the Danco purchaser was located to the street address of the nearest abortion provider included in the APC.

All analyses were conducted in Stata 16.1. Because the Danco data represent complete counts, we do not provide confidence intervals or other statistical tests for differences between groups or over time.

3. Results

3.1. Trends in estimated number of medication abortions and mifepristone purchasers

The total number of mifepristone purchasers increased, more or less steadily, from 971 in 2008 to 1114 in 2017 (Table 1). The 15% increase in purchasers was substantially smaller than the 73% increase in the estimated number of medication abortion, from 197,754 to 342,453.

The number of low-volume mifepristone purchasers declined over the 9-year period, 5% among those purchasing <100 and 14% among those purchasing <10 mifepristone tablets per year. Still, in all years, the majority of purchasers (52%–62%) acquired <100 mifepristone tablets, while 17% purchased <10 mifepristone tablets in 2017.

In contrast to the overall decline, there were increases in the number of low- and lowest-mifepristone purchasers between 2016 and 2017, from 548 to 574 (5% increase) among those purchasing <100 and from 179 to 194 (8% increase) among those purchasing <10. This was potentially due to the new FDA regimen that went into effect in March 2016. While abortion providers in North Dakota, Ohio and Texas were most impacted by this change, the total number of low-volume mifepristone purchasers in these three states combined only increased by 1, and the number purchasing <10 actually decreased by 3 (not shown).

A substantial minority of low- and lowest-volume mifepristone purchasers made higher volume purchases at some point. During the 2008–2011 period, 14% of facilities that purchased <100 doses of mifepristone at least once had purchased more than this amount during the 4-year period (not shown); the comparable figure for 2014–2017 was 17%. This same pattern applied to the lowest-volume purchasers (32% and 42%). In subsequent analyses, we focus on customers who were only ever low- and lowest-volume mifepristone purchasers, and we also exclude those who only purchased mifepristone in 2011 or 2017.

Among the 775 purchasers who never purchased more than 99 doses of mifepristone during the 2008–2011 period, 550 (71%)

Table 1Trends in estimated number of medication abortions and purchasers of <100 and <10 mifepristone pills per year, United States, 2008–2011 and 2014–2017

Year	Total		<100 medication abortions per year			<10 medication abortions per year		
	Number of purchasers	Estimated <i>N</i> of medication abortions	Number of purchasers	% of all purchasers	Estimated <i>N</i> of medication abortions	Number of purchasers	% of all purchasers	Estimated <i>N</i> of medication abortions
2008	971	197,754	604	62.2	16,428	226	23.3	1179
2009	958	216,900	565	59.0	15,522	198	20.7	1008
2010	982	236,301	565	57.5	14,469	201	20.5	1083
2011	998	245,055	553	55.4	14,606	196	19.6	1045
2014	1027	267,146	584	56.9	16,053	210	20.4	1124
2015	1042	287,289	570	54.7	16,107	190	18.2	1070
2016	1036	311,094	548	52.9	14,971	179	17.3	966
2017	1114	342,453	574	51.5	15,154	194	17.4	962
% Change 2008-2017	14.7	73.2	(5.0)		(7.8)	(14.2)		(18.4)

purchased this amount of mifepristone in 2 or more years (Table 2), and 249 (32%) purchased this amount of mifepristone in all 4 years (see Appendix table). During the more recent period, the total number of low-volume mifepristone purchasers declined slightly, but the number of repeat customers was slightly higher, 560 (75%).

The subset of facilities that never purchased more than 9 doses of mifepristone per year was more likely to be potential one-time customers. During the 2008–2011 period, 136 of the 304 lowest-volume customers (45%) purchased mifepristone in more than 1 year. This figure declined slightly, to 121, during the 2014–2017 period, though repeat customers now made up the majority (52%) of lowest-volume purchasers.

3.2. Mifepristone purchasers in nonmetropolitan medication abortion providers

In 2008–2011, all but 62 of the 1393 purchasers of mifepristone were located in metropolitan areas (Table 3); 47 were in micropolitan areas, and 15 were in rural areas. Mifepristone purchasers in micropolitan areas most commonly purchased enough for <10 medication abortions (n=22), but 12 purchased 100 or more. In rural areas, all but one customer purchased enough mifepristone to provide fewer than <100 medication abortions, and the majority, 9, purchased <10 doses. With the exception of the lowest-volume customer in micropolitan areas, the majority purchased mifepristone in more than 1 year.

In the more recent period, there were 5 more mifepristone purchasers in micropolitan areas compared to 2008–2011 and one less in rural areas. For both nonmetropolitan areas, the majority of facilities purchased 10 or more mifepristone pills but <100. At the same time, there was an increase in customers in micropolitan areas purchasing 100 or more mifepristone tablets in the 2014–2017 period.

The seemingly small increases in customer numbers in nonmetropolitan areas masked a substantial increase in the total number of doses of mifepristone purchased. In 2008, providers in micropolitan areas purchased enough mifepristone to provide 1842 abortions (Fig. 1); this increased 125%, to 4145, in 2017, with the rise concen-

Table 2Number of years low- and lowest-volume Danco customers purchased mifepristone, 2008–2011 and 2014–2017

	2008-2011		2014-2017	
	<100	<100		
# years	N	%	N	%
1	225	29.0	189	25.2
>1	550	71.0	560	74.8
Total	775	100.0	749	100.0
Only purchased in 2011 or 2017 (excluded)	96		120	
	< 10		< 10	
# years	N	%	N	%
1	168	55.3	114	48.5
>1	136	44.7	121	51.5
Total	304	100.0	235	100.0
Only purchased in 2011 or 2017 (excluded)	56		45	

trated between 2015 and 2017. Patterns were more varied in rural areas. Danco customers purchased enough mifepristone to provide 111 abortions in 2008, and this rose to 285 in 2011, a 156% increase. During the more recent period, 2014–2017, the estimated number of medication abortions in rural areas fluctuated between 210 and 274.

3.3. Mifepristone purchasers not captured by the Guttmacher Institute

In 2008, 14 purchasers of mifepristone were located more than 50 miles from the nearest abortion providing facility captured in the Guttmacher Institute's APC, and they purchased 81 mifepristone tablets (Table 4). An additional 45 purchasers of mifepristone were located 10 or more miles from the nearest Guttmacher abortion facility. In total, the 59 Danco customers not captured in the Guttmacher data provided as many as 1167 abortions.

Compared to 2008, in 2017, fewer mifepristone purchasers were located more than 50 miles from a facility included in the APC (n=8); an additional 25 were more than 10 miles from a facility included in the APC.

4. Discussion

This study suggests that increased reliance on medication abortions between 2008 and 2017 was largely due to increases in volume of mifepristone purchased per provider insofar as the overall number of low- and lowest-volume Danco customers decreased.

At the same time, the proportion of low- and lowest-volume purchasers who were likely one-time customers declined slightly, and the number purchasing <100 for more than 1 year increased slightly. Some facilities purchasing low volumes of mifepristone may have grown more comfortable with medication abortion provision and, in turn, became a regular source of care. There is also tentative evidence that the change in the FDA-approved medication abortion regimen may have motivated more health care providers to start offering medication abortion. It could be that the ability to purchase single tablets of mifepristone made it more economically feasible as opposed to purchas-

Table 3Low-volume mifepristone purchasers by population density, 2008–2011 and 2014–2017

		2008-2011				2014–2017				
		Estimated N of medication abortions per year				Estimated <i>N</i> of medication abortions per year				
	Total	<100		<10		Total	<100		<10	
		Total	$>1^a$	Total	$>1^a$		Total	$>1^a$	Total	$> 1^{a}$
Metropolitan	1331	822	522	329	123	1482	828	538	262	115
Micropolitan ^b	47	35	18	22	7	52	28	15	14	5
Rural	15	14	10	9	6	14	13	7	4	1
Total	1393	871	550	360	136	1548	869	560	280	121

^a Excludes those who only purchased mifepristone in 2011 or 2017.

 $^{^{\}rm b}\,$ Micropolitan areas are small urban areas with at least 10,000 residents but less than 50,000.

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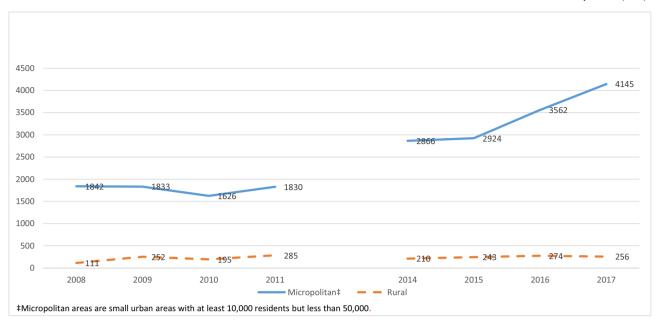


Fig. 1. Trend in estimated number of medication abortions in micropolitan and rural areas, 2008–2011 and 2014–2017.

ing 3-pill packs and potentially not using 2 of them. Additionally, the FDA approval of use through 70 days' gestation (instead of 49) may have contributed to the increase. Hopefully, future research will be able monitor patterns in low-volume purchasers to see if this increase continued.

Residents in nonmetropolitan areas sometimes have to travel hundreds of miles to obtain abortions [15,16]. We found that the amount of mifepristone purchased in micropolitan areas increased 125%. At a minimum, this likely meant several thousand women had options about the type of abortion they received; in areas that did not have procedural abortion providers, this development may have reduced travel to care and made abortion more accessible.

Table 4Number of mifepristone purchasers located > 50 and > 10 miles from nearest abortion facility known by the Guttmacher Institute, and estimated number of medication abortions, by volume and population density, 2008 and 2017

		2008	2017		
	'	Number	Number		
	Number of purchasers	Estimated <i>N</i> of medication abortions	Number of purchasers	Estimated N of medication abortions	
>50 miles					
Total	14	81	8	74	
<10		mifepristone	13	63	
4	14				
< 100		mifepristone	14	81	
8	74				
100 +		mifepristone	0	0	
0	0				
Metropolitan	6	36	2	26	
Micropolitan	5	21	3	12	
Rural	3	24	3	36	
>10 miles					
Total	59	1167	25	693	
<10		mifepristone	47	219	
16	44				
< 100		mifepristone	56	573	
22	140				
100 +		mifepristone	3	375	
3	509				
Metropolitan	38	921	19	528	
Micropolitan	18	222	3	117	
Rural	3	24	3	48	

This study has several limitations. We assumed each pill of mifepristone was used for one abortion. Even in the absence of state law, some health care providers may have adhered to the original FDA regimen, and we may have underestimated the number of low-volume providers (e.g., we assumed 150 pills represented 150 abortions when it only represented 50). Mifepristone has a shelf-life of 4 years, and "one-time" low-volume customers may have used mifepristone in multiple years and then gone on to purchase more. Because of imprecision in the geo coordinates of the Danco customers, we were only able to detect "unknown" mifepristone purchasers that were 10 or more miles from abortion providers known to Guttmacher. Undoubtedly, there were more Danco customers not captured in the Guttmacher studies (e.g., private practices in urban settings). Thirdly, prior research found indications that some health care systems may purchase mifepristone and distribute it to facilities in their network [17]. If this practice was widespread and, in particular, if low volumes of mifepristone were shared with network facilities, this study underestimates the actual number of low-volume mifepristone providers. However, low- and lowest-volume facilities tend to be stand-alone practices or independent health care providers [17].

Finally, the COVID-19 pandemic has impacted all aspects of health care, including abortion. Because medication abortion can involve little to no physical contact, it has become the preferred method for some providers and patients [18]. Moreover, Executive Orders in some states meant medication abortion was the only option that could be provided [19]. Of relevance to this study, some health care providers who did not previously provide abortions may have started offering medication abortion when state restrictions resulted in the closure of abortion clinics [19]. In turn, the number of low-volume providers may have increased because of the pandemic, if only temporarily. These developments during the pandemic speak to the long-standing and continued need to integrate medication abortion training into a wider range of medical specialties, including family medicine, internal and emergency medicine and pediatrics.

While there is no evidence that the number of low- and lowest-volume mifepristone purchasers substantially increased during the study period, low-volume abortion providers may still have played an important role for the individuals and communities they served. As federal and state lawmakers continue to constrain access to abortion by imposing restrictions on abortion clinics [20,21], the extent to which abortion can be provided by a wider network of health care

practitioners, especially those in small or private practices, may be increasingly important.

Acknowledgments

I thank Abigail Weiss of Danco Laboratories, and Megan Donovan, Joerg Dreweke and Kathryn Kost, all of the Guttmacher Institute, for providing feedback on earlier drafts of this manuscript. I also thank Noah Zazanis, formerly of the Guttmacher Institute, for cleaning the data and getting them into an analyzable format.

Funding

This research was supported by a grant from the Society of Family Planning Research Fund (SFPRF). The views and opinions expressed are those of the author and do not necessarily represent the views and opinions of SFPRF.

Declaration of competing interest

The author declares that she has no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix

Appendix tableNumber of years low- and lowest-volume Danco customers purchased mifepristone, 2008–2011 and 2014–2017

	2008-	2011	2014–2017	
	<100		<100	
# years	N	%	N	
1	225	29.0	189	25.2
>1	550		560	
2	171	22.1	184	24.6
3	130	16.8	162	21.6
4	249	32.1	214	28.6
Total	775		749	
Only purchased in 2011 or 2017 (excluded)	96		120	
	<10		<10	
# years	N	%	N	
1	168	55.3	114	48.5
>1	136		121	
2	75	24.7	64	27.2
3	38	12.5	39	16.6
4	23	7.6	18	7.7
Total	304		235	
Only purchased in 2011 or 2017 (excluded)	56		45	

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