



american society for  
emergency contraception

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## EC ON THE SHELF: Real-World Access in the OTC Era

### Summary and Key Recommendations

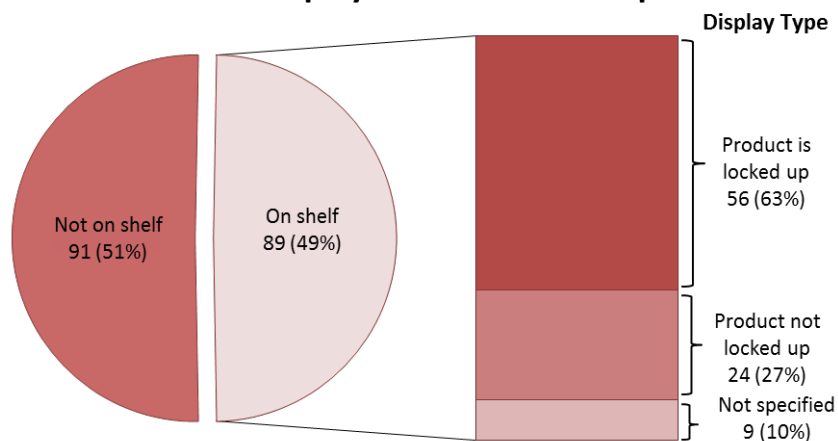
Although current regulations allow Plan B One-Step® to be sold on the shelf with no age or point-of-sale restrictions, our survey found that, since the regulations took effect, **only half of stores stock the product on the shelf**. Even among stores that stock Plan B One-Step® on the shelf, **two-thirds lock the product in a portable box or fixed case** which must be unlocked by a store employee, which can bring unwanted and uncomfortable attention to the purchase.

Some store personnel said that they did not know that Plan B One-Step® could be sold on the shelf, while others stated that **the product is locked up or held behind the counter due to its high cost**. Soon, generic EC products will be approved for sale on the shelf as well; it remains to be seen when and if this change will substantively improve ease of access to EC in the United States in the near term.

### Findings in Brief

- Half of the stores in this sample (51%) did not stock Plan B One-Step® on the shelf
- Among stores that did stock Plan B One-Step® on the shelf, two-thirds locked the product in a case or box that must be unlocked by a store employee
- In only 13% of all stores could Plan B One-Step® be obtained directly on the shelf (either in a cardboard box alone or in a plastic clamshell package) without seeking help from an employee
- 14% of participants said that finding Plan B One-Step® in the store was “Very difficult”

### Shelf Display of Plan B One-Step



## Introduction

Access to levonorgestrel emergency contraception (LNG EC), such as Plan B One-Step® and Next Choice One-Dose™, in the United States has been characterized by a complicated, frequently-changing regulatory status fraught with political interference. Although there has never been any scientific evidence to support age or point-of-sale restrictions on LNG EC, the product has changed from prescription-only status to dual-label status requiring a prescription for those under the age of 18 (then later, 17) and proof of ID for those eligible for non-prescription sale. In August 2013, the branded LNG EC product (Plan B One-Step®) was approved for full over-the-counter sale with no age or point-of-sale restrictions, while the generic versions remained behind the counter with non-prescription sale restricted to those aged 17 or older showing proof of age. In February 2014, the FDA issued a letter stating that manufacturers of generic LNG EC products may apply to sell their products directly on the shelf. The product label will state that it is intended for use by those aged 17 and older (thus nominally protecting Teva's exclusivity on full OTC sale for Plan B One-Step®), but proof of age will not be required to purchase the product.

While the August 2013 regulatory change allowing unrestricted sale of Plan B One-Step® was a positive (though incremental) step forward for EC access, complications remain. Confusion about the regulatory status of EC, as well as the high price of Plan B One-Step® (\$48 on average) has led to great variation in individuals' experiences purchasing the product. From September 2013 to March 2014, ASEC conducted a nation-wide survey to assess how stores were stocking Plan B One-Step® and generic EC products, with a particular focus on whether Plan B One-Step® was available for unrestricted sale on the shelf as the August 2013 regulations allowed, whether the product was enclosed in a case that had to be unlocked by an employee, and how easy or difficult it was to locate EC in the store. Our goal is to describe access to LNG EC before the latest set of regulations (from February 2014) takes effect, and to monitor how access evolves with yet another regulatory change.

## Methods and Participants

ASEC distributed an online survey via our list serve and through partner organizations. Respondents were asked to visit local stores and describe how EC was sold in that store using a standardized questionnaire. Data for 180 stores in 29 states were provided by 88 individuals. In our survey, sale "on the shelf" included any type of packaging or box, even locked cases, as long as the product was in view and not sold exclusively behind the pharmacy counter. This is a relatively small convenience sample and is not nationally representative; however, it provides a useful snapshot of how stores are displaying Plan B One-Step® and the experience that individuals have in purchasing the product.

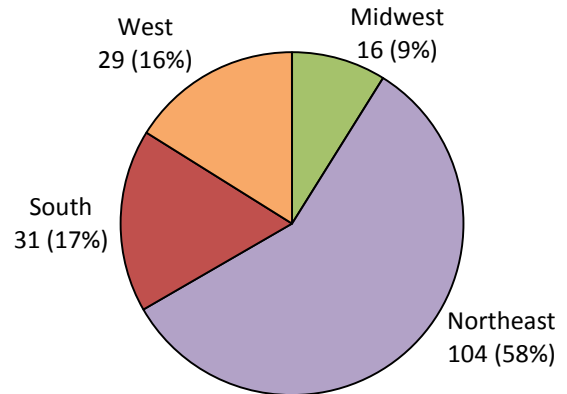
## Geographical Distribution

More than half of our sample is located in the Northeast; the states with the most reports were New York (45 stores) and Pennsylvania (40).

### States with $\geq 10$ Pharmacy Listings



### Listings by Region



## Store Type

The types of stores included in this sample included dedicated pharmacies, grocery stores, and big-box stores (such as Target or Walmart). The vast majority of stores in this sample (89%) are part of a chain of stores; the remaining 11% were independent pharmacies. Six locations were excluded from the sample because they were not retail outlets (these included student health facilities and outpatient pharmacies).

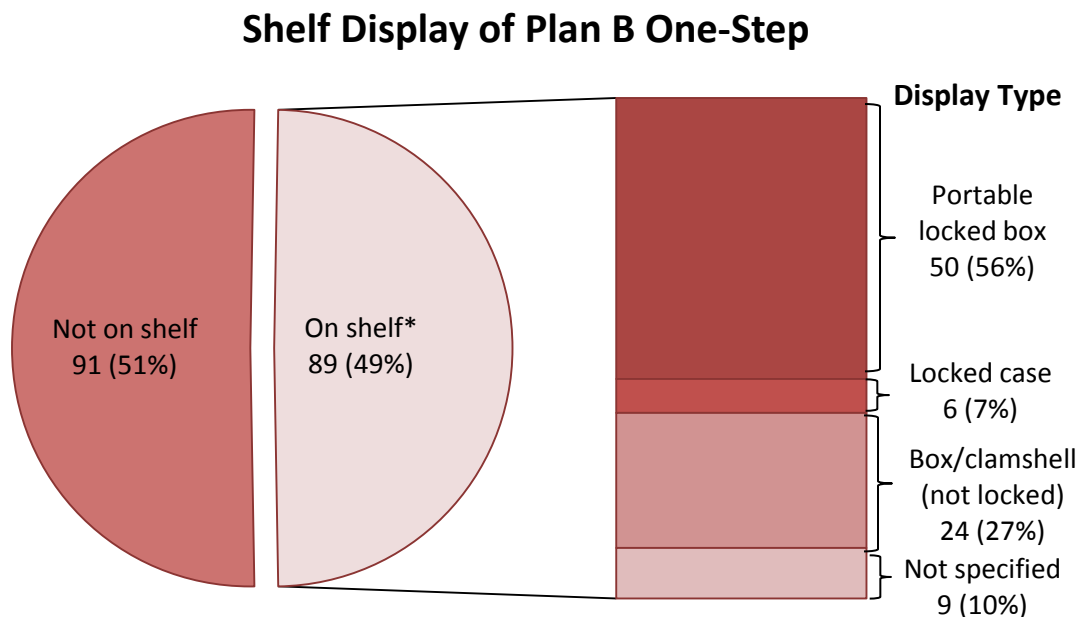
### Listings by Store Type



## Results

### Stores stocking Plan B One-Step® on the shelf

Plan B One-Step® was available on the shelf in only half (49%) of the stores in our sample. Among stores that did sell Plan B One-Step® directly on the shelf, in 63% of stores the product was in a locked display of some kind, requiring assistance from store personnel. In 56% of stores selling Plan B One-Step® on the shelf, the product was encased in a large plastic box which the customer had to carry to the register or the pharmacy counter to be unlocked by store staff. In another 7% of stores, the product was in a locked fixed case in the aisle, requiring the customer to summon a staff member to the aisle to unlock the product. In only 27% of stores stocking Plan B One-Step® on the shelf (13% of all stores) could the consumer purchase the product, displayed either in its cardboard package alone or in a plastic clamshell package, without needing to ask store personnel for help.



\*Includes any display not behind the pharmacy counter, including locked case or box

In stores that stock Plan B One-Step® on the shelf, it was most commonly found in the family planning aisle, near condoms and pregnancy tests (77%). In 12% of these stores it was displayed in front of the pharmacy counter, and in 10% of stores the product was sold in the feminine care aisle. One respondent reported that Plan B One-Step® was sold behind the front register, and another found it at the photo counter.

### Stores not stocking Plan B One-Step® on the shelf

*"I asked the pharmacist why [Plan B One-Step was] not on shelf and she said she thought it was a security issue due to the price and the store policy was to keep it behind the counter even though no age restrictions."*

*-Participant comment about a chain grocery store/pharmacy, Tennessee*

Half of the stores in this sample did not stock Plan B One-Step® on the shelf; the majority of these stores stocked the product behind the counter, although a small number did not stock EC at all. Sixteen respondents (9% of total) were incorrectly told that ID is required to purchase Plan B One-Step®, and when they asked about the minimum age for non-prescription purchase, these individuals reported a range of 13 to 18.

None of the six individuals who identified themselves as male were specifically told that they could not buy EC, although one respondent reported:

*“Reason it is behind the shelf: Wasn't the usual ‘because people steal it’ or ‘it's our store policy’ it was ‘The pharmacist wants to make sure everything is “ok” with the situation...wants to make sure the people know how to use it.’ Especially mentioned was a “worry” when men want to purchase EC...”*

*- Participant comment about an independent pharmacy, Iowa*

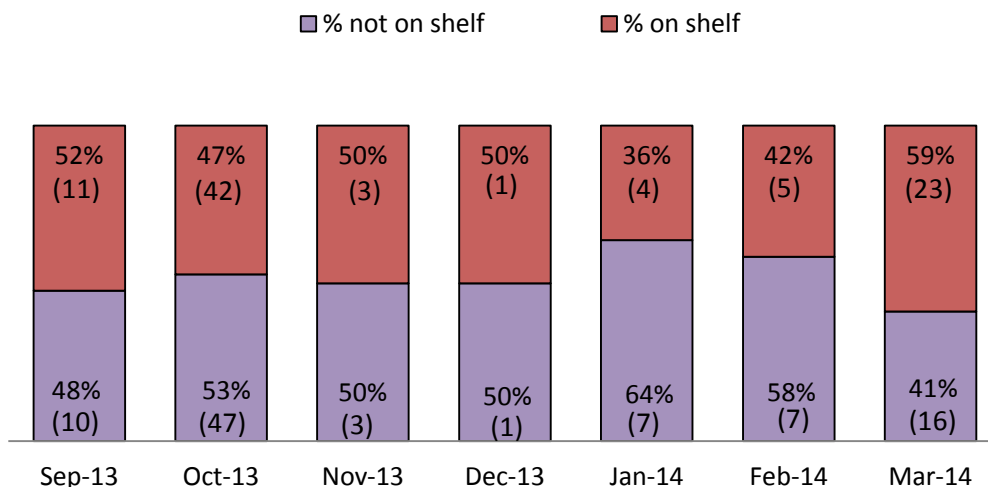
### Changes in stocking practices over time

*“Over the counter Plan B was sold out for several weeks at a time in November and December 2013.”*

*- Participant comment about a chain pharmacy, New York City*

Since the August 2013 regulatory change that allowed Plan B One-Step® to be sold without age or point-of-sale restrictions on store shelves, the situation has continued to evolve. One significant change is in the packaging of Plan B One-Step®. When the FDA decision was announced, Teva Pharmaceuticals (the manufacturer of Plan B One-Step) worked to get the product onto store shelves as quickly as possible; this meant that the first shipments of the newly-labeled product appeared in stores in just the cardboard box, with no additional theft-resistant packaging (perhaps motivating stores to lock the product up). A few weeks later, the company began to ship the product in a plastic clamshell package, which is intended to deter theft. Given that many retail outlets cite the high cost of the product (and subsequent theft risk) as a reason to hold it behind the counter, this change in packaging should have improved the willingness of stores to stock the product on the shelf. This sample of stores is relatively small and not nationally representative; however, it is of interest to note that the proportion of stores in our sample stocking Plan B One-Step® on the shelf in March 2014 (59%) is not dramatically higher than that in October 2013 (47%).

### Stocking of Plan B One-Step, by Month



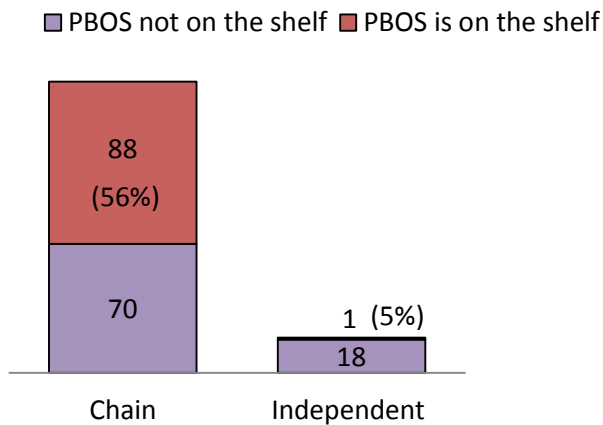
## Stocking practices by store and store type

*“One person said that it could not be put out on the shelf. The other person who appeared to be the manager said that he was not going to put a \$60 product on the shelf where it could be stolen.”*

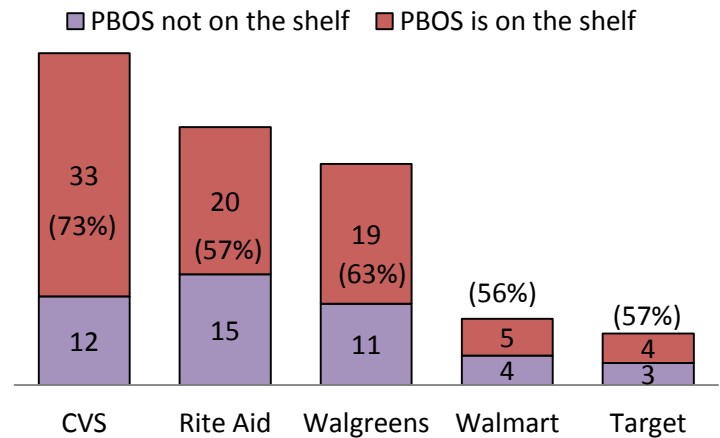
*- Participant comment about an independent pharmacy, New York City*

Slightly more than half (56%) of chain stores in our sample stocked Plan B One-Step® on the shelf at the time of the survey. This sample includes only 19 independent stores (11% of total), and only one of these stocked Plan B One-Step® on the shelf. Among the most-frequently represented chain stores in our sample, Plan B One-Step® was most commonly seen on store shelves in CVS (73% of stores) and Walgreens (63%).

### Stocking of Plan B One-Step, by Store



### Stocking of Plan B One-Step, by Store



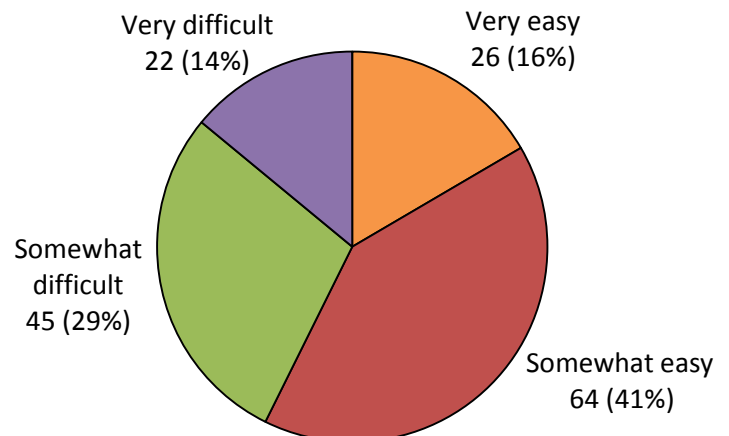
## Consumer experience

*“It was a very awkward interaction...I had to explain to the Pharmacist - in front of other people in line - in three different ways what I was looking for. First I said Plan B, then I said Emergency Contraception, then I said the pill you take after you have unprotected sex. Let me note that I had this interaction with the Pharmacist only after I asked the cashier at the pharmacy who went and got the Pharmacist.”*

*- Participant comment about a chain pharmacy, Washington DC*

More than half (57%) of the respondents to this survey reported that the experience of locating Plan B One-Step® was very or somewhat easy. However, it is important to note that 14% described the experience of finding a product that is approved for unrestricted sale on the shelf as “very difficult”.

### Consumer Experience Locating Plan B One-Step at the Store



## Conclusion

The regulatory changes governing sale of LNG EC have been complicated and difficult for consumers, retailers and manufacturers to track and keep up with. Although each regulatory change has incrementally improved access, even the approval of Plan B One-Step® for unrestricted sale has not yet proven to make access to EC easy for all consumers, as only half of the stores in our sample stocked the product on the shelf at the time of the survey. Among stores that did stock Plan B One-Step® on the shelf, two-thirds locked the product in a fixed case or portable locked box, requiring that consumers seek help from store personnel. When EC was encased in a portable locked box, we considered it “on the shelf” for the purposes of this report; while this mode of display may offer easier access than the product being held behind the pharmacy counter, it may present an undue barrier to the purchase of EC. For many women, carrying a large security case may call attention to a purchase that they may want to keep private, and it requires an additional level of interaction from store staff which may make women feel uncomfortable. When questioned about why the product was locked up, or not on the shelf at all, store staff frequently cited the high cost of the product, “store policy”, or stated that they did not know that it could be sold directly on the shelf. Although these findings come from a convenience sample of 180 stores and are not nationally representative, they provide a useful insight into the experiences of individuals who purchase EC every day at retail outlets.

The most recent shift in the regulatory landscape will allow generic LNG EC products to be sold on store shelves. Technically, these products will be intended for use by women aged 17 and older (and the Drug Facts on the package will state this), although proof of age will not be required. It remains to be seen how quickly, and indeed if, these products will appear directly on store shelves. Although the generic EC products are somewhat less expensive than the branded product (\$41 on average, compared with \$48 for the branded product), it is likely that many stores will consider EC a high-cost product, and continue to keep EC behind the counter or locked up. Unrestricted on-the-shelf regulatory status offers the potential for privacy and ease of access, yet the high cost of EC often means that barriers remain.

While we continue to monitor how access to EC evolves under the new regulations, we encourage colleagues and consumers to look for EC in every store. When it is not available on the shelf, ask store managers why it is not, ensure that they understand that current regulations allow the product to be sold on the shelf with no restrictions, and demand better access for all women.