

No. 12-35221, 12-35223

**IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT**

STORMANS, INC., DOING BUSINESS AS RALPH'S THRIFTWAY, *ET AL.*,
Plaintiffs-Appellees,

v.

MARY SELECKY, *ET AL.*,
Defendant-Appellants,

and

JUDITH BILLINGS, *ET AL.*,
Intervenors-Appellants

On Appeal from the United States District Court
for the Western District of Washington
No. 3:07-cv-05374-RBL – Hon. Ronald B. Leighton

SUPPLEMENTAL BRIEF FOR APPELLEES

Luke W. Goodrich
The Becket Fund for Religious Liberty
3000 K St. NW Ste. 220
Washington, DC 20007

Steven H. Aden
Alliance Defending Freedom
15100 N 90th Avenue
Scottsdale, AZ 85260

Kristen K. Waggoner
Steven T. O'Ban
Ellis, Li & McKinstry PLLC
2025 First Avenue, Penthouse A
Seattle, WA 98121-3125

Michael W. McConnell
559 Nathan Abbott Way
Stanford, CA 94305

Counsel for Plaintiffs-Appellees

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INTRODUCTION

On August 8, 2013, this Court ordered supplemental briefs addressing the effect of the Food and Drug Administration's (FDA's) decision "to make Plan B One-Step available as a nonprescription product without point-of-sale or age restrictions." Order at 3. In particular, the Court ordered the parties to address "whether this case has become moot." *Id.*

As explained below, the FDA's decision does not make this case moot, because it does not affect the status of *ella* or several other brands of Plan B—which are still available only through pharmacies, and only with a prescription or proof of age. Thus, the Regulations still apply to those drugs and still require Plaintiffs to stock and dispense them in violation of their religious beliefs.

However, the FDA's decision does make Plan B even more widely available, without the need to obtain a prescription or see a pharmacist. Thus, there is even less reason for Regulations that would force pharmacies and pharmacists to stock and dispense Plan B in violation of their religious beliefs.

FACTUAL BACKGROUND

The FDA has approved several different brands of emergency contraception with different rules governing their availability. At least five different brands of emergency contraceptives are referred to in the

briefs by the generic term “Plan B”: (1) Plan B One-Step; (2) Next Choice One Dose; (3) My Way; (4) Levonorgestrel Tablets; and (5) Next Choice. All of these drugs contain the hormone levonorgestrel. Some consist of a single pill containing 1.5 milligrams of levonorgestrel; others consist of two pills containing .75 milligrams each. At the time of trial, all versions of Plan B were available only through a pharmacy. Patients under seventeen needed a prescription; patients seventeen or older did not. ER 82.

In addition to the various versions of Plan B, the FDA has also approved *ella*, which contains ulipristal acetate. *Ella* is effective for a longer time period than Plan B, but it is available only by prescription.

On June 28, 2013, the FDA approved an application to make Plan B One-Step available “as a nonprescription product without point-of-sale or age restrictions.” Order at 3. In other words, Plan B One-Step is no longer required to be kept behind the pharmacy counter and dispensed by a pharmacist, but can be made available on store shelves like other over-the-counter drugs. The FDA’s decision, however, does not affect the status of Next Choice One Dose, My Way, Levonorgestrel Tablets, Next Choice, or *ella*—all of which are still available only from a pharmacy.¹

¹ One-pill generic versions of Plan B One-Step, such as My Way and Next Choice One Dose, may soon be available over-the-counter to patients aged 17 or older. See Deborah Kotz, *Teva Gets Exclusivity on Plan*

The following chart summarizes the current availability of the various types of emergency contraception:

Name of Drug	Available Over-the-Counter without Restrictions	Available only from Pharmacy; Patients under 17 Need Prescription	Available by Prescription Only
Plan B One-Step	X		
Next Choice One Dose		X	
My Way		X	
Levonorgestrel Tablets		X	
Next Choice		X	
<i>ella</i>			X

There is still an active market for all of these versions of emergency contraception. For example, Plan B One-Step is a name-brand drug that is more expensive than other forms of Plan B; thus, some patients will still prefer less expensive generics.² Similarly, some forms of insurance

B Contraceptive, The Boston Globe, July 24, 2013. But this change has not taken effect yet, and two-pill versions will remain behind the pharmacy counter. *Id.* Until at least 2016, Plan B One-Step will be the only brand available over-the-counter without age restrictions. *Id.*

² American Society for Emergency Contraception, *The Cost of Emergency Contraception: Results from a Nationwide Survey*, 1 (July 2013), available at <http://ec.princeton.edu/ASECPricingReport.pdf>.

may not pay for Plan B One-Step, or may require subscribers to get a prescription in order to obtain reimbursement, leading patients to depend on other versions of Plan B.³ Finally, *ella* can be taken longer after unprotected intercourse than Plan B; thus, some patients will still prefer *ella* over any form of Plan B.⁴

ARGUMENT

I. This Case Is Not Moot.

A case becomes moot on appeal “when the issues presented are no longer live or the parties lack a legally cognizable interest in the outcome.” *Council of Ins. Agents & Brokers v. Molasky-Arman*, 522 F.3d 925, 933 (9th Cir. 2008) (quoting *Outdoor Media Group, Inc. v. City of Beaumont*, 506 F.3d 895, 900 (9th Cir. 2007)). This occurs only if “interim relief or events have completely and irrevocably eradicated the effects of the alleged violation,” *Chang v. United States*, 327 F.3d 911, 918 (9th Cir. 2003), and “only if it [is] absolutely clear that the litigant

³ See Alexandra Sifferlin, *Plan B One-Step Now for Sale: What you Should Know*, Times, August 1, 2013, available at <http://healthland.time.com/2013/08/01/plan-b-one-step-now-for-sale-what-you-should-know/>.

⁴ *Ella* Patient Brochure (August 21, 2013), available at http://www.ella-rx.com/pdf/ella_PatientBrochure.pdf.

no longer ha[s] any need of the judicial protection that it sought.” *Jacobus v. Alaska*, 338 F.3d 1095, 1102-03 (9th Cir. 2003).

Here, the FDA’s decision has not eradicated the effects of the Regulations or eliminated the need for judicial protection. Rather, because other versions of Plan B and *ella* are still available only from pharmacies, the Regulations still require Plaintiffs to violate their religious beliefs, and still harm them in several ways.

First, the Stormans’ pharmacy, Ralph’s, is still subject to three pending investigations for violating the Stocking and Delivery Rules. Resp. Br. 42-43, 97. The Board has said that Plaintiff is in “outright defiance of the stocking rule”; two Board witnesses testified that Plaintiff is acting illegally; and the Chairman of the Board testified that the “only option” is “revoking [the] license of [Plaintiff’s] pharmacy.” *Id.* at 96. The FDA’s decision does not change any of this. In fact, the complaints against Ralph’s were filed in 2006, several years before the FDA approved Plan B One-Step. *Id.* at 41-43. Thus, the pending investigations involve a different version of Plan B—one that is still available only from pharmacies. Accordingly, Ralph’s is still subject to punishment under the Regulations, and the case is not moot. *See Jacobus*, 338 F.3d at 1104 (case is not moot where plaintiffs could still be punished under challenged law).

Second, regardless of its past conduct, Ralph's remains in violation of the Regulations going forward because it cannot stock or dispense *any* version of Plan B. The fact that Plan B One-Step is now available over the counter does not change how the Regulations apply to Ralph's. If a patient requests another version of Plan B from the pharmacy—whether for reasons of cost, insurance, or test-shopping—Ralph's will not stock or dispense the drug. Thus, it will still be in violation of the Stocking and Delivery Rules, and will still be subject to revocation of its pharmacy license.

Third, the FDA's decision with respect to Plan B One-Step has no effect on *ella*, which is still available only by prescription. *Ella* is effective for a longer time period than any version of Plan B. Thus, at least two patients have already requested it from Ralph's (SER 431) and more may continue to do so. Because Ralph's cannot stock or dispense *ella*, it will continue to be in violation of the Regulations.

Finally, for the same reasons, the Regulations continue to harm Ms. Mesler and Ms. Thelen. As noted above, despite the increased availability of Plan B One-Step, there is still demand for other versions of Plan B. Although some pharmacies may be able to accommodate individual pharmacists by stocking Plan B One-Step (which need not be dispensed by a pharmacist), others may not—either because some of their patients

cannot afford it, or because some of their patients' insurance will not cover it. Thus, the Regulations still limit Ms. Mesler and Ms. Thelen "to employment only at pharmacies able to accommodate their religious views." *Stormans, Inc. v. Selecky*, 586 F.3d 1109, 1122 (9th Cir. 2009).

The same is true of *ella*. Because Plan B One-Step is not a valid substitute for *ella*, pharmacies that receive requests for *ella* must stock and dispense that drug. And if those pharmacies employ conscientious objectors like Ms. Mesler and Ms. Thelen, they must either terminate those employees or violate the Regulations. Resp. Br. 27-29.

In sum, despite the over-the-counter availability of Plan B One-Step, the Regulations still require Plaintiffs to stock and dispense other versions of Plan B and *ella* on pain of termination or loss of their pharmacy license. That is a "concrete and particularized" injury; it is traceable to the Regulations; and it would "certainly be ameliorated should the [Regulations] be held unconstitutional." *Stormans*, 586 F.3d at 1121. Thus, the case is not moot.

II. Plan B Is Now Even More Widely Available.

That is not to say that the FDA's decision is irrelevant to this case. Far from it. A central issue in this case has always been whether there is a problem of access to Plan B. Much of the evidence at trial focused on access to Plan B. Multiple Board witnesses testified about access to

Plan B. And as the district court found, “the weight of the testimony at trial strongly supports the conclusion that there was no problem of access to Plan B or any other drug, either before or after the rulemaking process.” ER 86.

However, now that the FDA has approved Plan B One-Step for over-the-counter availability, Plan B will be even more widespread. For example, several of Intervenors’ alleged refusal stories involved patients who tried to obtain Plan B without a prescription, which was illegal at the time. *See, e.g.*, Resp. Br. 33 (emergency contraception in Redmond); *id.* at 38 (Andreini). Others involved patients who did not want to request it at “multiple pharmacies.” Interv. Reply at 7. Now, however, neither a prescription nor a pharmacy is necessary. It can be obtained on store shelves whether there is a pharmacy or not. As one spokesperson for Planned Parenthood put it: “We are incredibly excited about this development Access alongside other medications, like Tylenol, will make [Plan B] *incredibly more available to women.*”⁵

⁵ Lisa M. Krieger, *‘Morning after’ pill goes on sale Thursday in pharmacies and grocery stores, available to anyone*, San Jose Mercury News, July 31, 2013 (emphasis added), available at http://www.mercurynews.com/science/ci_23770130/morning-after-pill-goes-sale-thursday-pharmacies-and.

Given that Plan B is so widely available, there is no reason to force Plaintiffs to stock and dispense it in violation of their religious beliefs. As the district court found, it is undisputed that “[n]one of Plaintiffs’ customers has ever been denied timely access to emergency contraception.” ER 61. Beyond that, the State has stipulated that Plaintiffs’ conduct “do[es] not pose a threat to timely access to lawfully prescribed medications . . . includ[ing] Plan B.” SER 1619. Thus, forcing Plaintiffs to dispense Plan B in violation of their religious beliefs is completely unnecessary and does not advance any legitimate governmental interest. Resp. Br. 123-25.

CONCLUSION

The judgment of the district court should be affirmed.

Luke W. Goodrich
The Becket Fund for Religious Liberty
3000 K St. NW Ste. 220
Washington, DC 20007

Steven H. Aden
Alliance Defending Freedom
15100 N 90th Avenue
Scottsdale, AZ 85260

Respectfully submitted,

s/ Kristen K. Waggoner

Kristen K. Waggoner
Steven T. O’Ban
Ellis, Li & McKinstry PLLC
2025 First Avenue, Penthouse A
Seattle, WA 98121-3125

Michael W. McConnell
559 Nathan Abbott Way
Stanford, CA 94305

**CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME
LIMITATION, TYPEFACE REQUIREMENTS, AND
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This brief complies with the type-volume limitation set forth in this Court's Supplemental Briefing Order of August 8, 2013, because this brief contains 1,896 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

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s/ Kristen K. Waggoner

Kristen K. Waggoner
Ellis, Li & McKinstry PLLC
2025 First Avenue, Penthouse A
Seattle, WA 98121-3125
(206) 682-0565
kwaggoner@elmlaw.com

Counsel for Plaintiffs-Appellees

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system on August 22, 2013.

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

s/ Kristen K. Waggoner

Kristen K. Waggoner
Ellis, Li & McKinstry PLLC
2025 First Avenue, Penthouse A
Seattle, WA 98121-3125
(206) 682-0565
kwaggoner@elmlaw.com

Counsel for Plaintiffs-Appellees