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**Via Electronic Submission and U.S. Mail**
Federal Trade Commission
Office of the Secretary
600 Pennsylvania Avenue NW
Suite CC-5610 (Annex C)
Washington, DC 20580

*Re:* Contact Lens Rule, 16 CFR Part 315, Project No. R511995

Dear Commissioners:

The Commission's notice of proposed rulemaking requested that LD Vision Group (LensDiscounters.com) provide further evidence to support the recommendations of its original comment. Please see the attached comment, which further explains LensDiscounters.com's position and provides examples of the unfair practices sought by the Commission.

Sincerely,

Aaron Gott
Bona Law PC

Attachments: LD Vision Response to the Commission's Notice of Proposed Rulemaking and Exhibits

## Contact Lens Rule, 16 CFR Part 315, Project No. R511995

# LD VISION GROUP RESPONSE TO THE COMMISSION'S NOTICE OF PROPOSED RULEMAKING

LD Vision Group, Inc. ("LensDiscounters.com") previously provided the Commission its comments on the Contact Lens Rule, relaying its pragmatic experiences and advising on how the rule could be strengthened. The rule, though an admirable step toward the creation of a free and open consumer market for contact lenses, remains plagued by manufacturers and prescribers acting to frustrate and confuse consumers, while obstructing the ability of low-cost retailers like LensDiscounters.com to fairly compete. These obstructionist acts artificially drive up costs for contacts and put consumers' ocular health at risk.[1]

The Commission's notice of proposed rulemaking expressed that it lacked adequate examples to fully assess LensDiscounters.com's comments and requested further information. LensDiscounters.com therefore provides this supplemental comment to better inform the Commission on the issues it raised. LensDiscounters.com is committed to providing information to assist the Commission in its task of revising the Contact Lens Rule to better protect consumers as Congress intended.

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1 There is a correlation between a free market that provides low-cost options for contact lenses and a consumer's overall ocular health. Where a consumer has unbridled choice—they benefit, not only financially, but physically as well. *See* http://www.americanthinker.com/articles/2016/12/lame_duck_congress_is_after_your_contact_lenses.html "Throughout most of Europe and Japan consumers are not even required to have a prescription to purchase contact lenses. Since the prescription policies have gone into effect, statistics have shown no increase in contact-related eye infections. Even while Johnson & Johnson is supposedly so worried about the eye health of patients in America, the company shows none of the same concerns when selling the very same contact lenses without prescriptions to the Europeans and the Japanese." *See also* http://www.americanthinker.com/articles/2016/05/a_concrete_example_of_what_cruz_calls_the_washington_cartell.html "Contact lenses are consequently cheaper in Europe and Japan than for the 40 million Americans who regularly use them, at a cost of $4 billion a year." *See also* https://keepcontactlenschoice.org/in-the-news/contact-lenses-get-expensive-legislation-passes/ "Ironically, in European countries and in Japan, it is easier to get contact lenses. In fact, prescriptions are not needed in Japan. With more than 180 million people wearing contact lenses worldwide, it is a sad state of affairs that so many around the world live in a more economically free society when it comes to eye care." *See also* https://spectator.org/6_clear-eyed-view-contact-lens-debate/ "The simplest solution would be to do away with the gate keepers altogether and allow the purchase of contact lenses without a prescription. It works just fine that way in Europe and Japan, but manufacturers and doctors nevertheless protect their legal mandate through lobbying by citing health concerns, even as the same manufacturers happily sell to overseas markets without the same requirements." *See also* https://www.theblaze.com/contributions/the-war-on-affordable-contact-lenses/ "In fact, in Japan and most of Europe, contact lens users aren't even required to receive a prescription; yet, research from Dr. Paul B. Donzis, a professor of ophthalmology at UCLA, found that most of these countries actually have significantly lower contact incidence reports than does the United States."

## PASSIVE VERIFICATION

In summarizing issues related to the rule's passive verification requirements, the Commission cited LD Vision Group's comment that prescriptions received are not always complete or correct, making it difficult for consumers to purchase contacts from third-party sellers. *See* NPR at 27. The Commission stated it lacked "robust empirical data" on the subject, and expressed a desire to obtain additional data independent of the surveys delivered, since the reliability of such surveys suffered from methodological limitations making none of them definitive. *See id.* at 25, 28. Ultimately, the Commission found, from the reliable evidence it had, that it was merely "possible that some of these consumers received incomplete or otherwise problematic prescriptions." *See id.* at 28. LensDiscounters.com thus provides the Commission concrete examples of incomplete and problematic prescriptions it has been provided. It hopes these examples suffice to demonstrate the various ways prescribers undermine the rule.

LensDiscounters.com **attaches Exhibit A** and provides the following annotations to that exhibit:

| Ex. Pages | Comment |
|---|---|
| A-1 | The doctor wrote a BC (base curve) of 8.5 and a dia of 14.1 however this lens is ***only*** made in 8.6 and 14.2. The patient would not find BioTru ONEday brand lenses in 8.5/14.1. From our experience, doctors hope to get a call from their patients asking about the discrepancy and presenting an opportunity to solicit a sale, which they would have otherwise not received. |
| A-2 | The doctor wrote 8.7 and 14.5 but this product is only made in 8.6/14.2 |
| A-3 | This Vision Source doctor actuallly wrote on the prescription "CooperVision-Private Label Aqua Clear Toric 6 pack" but with no notation of the main brand "Biofinity Toric." |
| A-4 | The Rx is written for "Sofmed Breathables Toric" which is CooperVision's "Avaira Toric" and not to be confused with Sofmed Breathables XW Toric which is CooperVision's Biofinity Toric. |
| A-5 | The watermark "VOID" aside, this doctor writes "SMXW" for the lens name. We can assume the OD (right eye) is Sofmed Breathables XW, which is a private label for Biofinity. The doctor wrote 8.5/14.2 but it is only made in 8.6/14.0. For the left eye, the doctor wrote a toric/astigmatism prescription, but did not indicate SMXW Toric, which is the private label for Biofinity Toric. One could deduce that it should be Biofinity Toric which is only made in 8.7/14.5—the doctor here wrote 8.5/14.5. |
| A-6 | To make this prescription complete, there should be an ADD power parameter listed of Low, Mid, or High. Further, the doctor wrote the lens name as "oasys presbyopic" and the manufacturer as "vis." |

| Ex. Pages | Comment |
|---|---|
| A-7–A-9 | This doctor did not adjust the standard [eyeglass refraction] to the appropriate contact lens parameters. It would appear that the doctor didn't actually do a contact lens fitting. There's just a note to the dispenser under recommendations "Accuvue Oasis CL" with an 8.8 BC. The "Acuvue Oasys" that he is referring to is a spherical lens. But the parameters listed are for toric/astigmatism type lenses (sphere would have just the power, but this includes a cylinder and axis). But the "or Accurvue Toric" recommendation doesn't specify exactly which toric version of Acuvue lenses and Acuvue toric options like Acuvue Oasys for Asitigmatism do not come in an 8.8 BC. All of Acuvue's and most other brand's soft toric lens options are not made in axis' that are in 5 degree steps—the doctor wrote 135 for the left eye. Lastly, soft toric lenses aren't made in a -0.50 cylinder option either which he listed. |
| A-10 | The Biofinity Toric lens is not made in a 075 axis. It would have to be 70 or 80. |
| A-11 | The doctor did not write the BC which could be 8.4 or 8.8 in this brand. |
| A-12 | This one is simply difficult to discern—Most people could tell that it's both the spectacle lens rx (SRX) and the "final cl rx" is compressed on one line. Where the contact lenses are for the right eye only and should be Acuvue Oasys 8.4 -2.00 (complete info). It is unclear why the Refills indicate "0". It doesn't have any expiry date listed, which according to the Fairness Rule, this prescription is valid for 1 year except for Florida, Mayland, Minnesota, Mississippi, New Mexico, Utah and Washington, which by its state laws are good for two years. |
| A-13 | It's written for SMXW, abbreviated from Sofmed Breathables XW, a private label for Biofinity. |

The receipt of incorrect or incomplete prescriptions force LensDiscounters.com to seek further verification of a consumer's prescription with the doctor/prescriber. It has become an increasingly common experience that such attempts at verification fail because the doctor/prescriber will respond to a request for verification by indicating, for example, that—"patient not found." ***See* Exhibit B**. LensDiscounters.com is then forced to approach the consumer for a copy of the original prescription, a request that typically undermines the consumer's confidence in LensDiscounters.com's competency. Where the consumer complies, providing the prescription, the prescription invariably shows the consumer is in fact a patient of the doctor/prescriber.

The rule's efficacy is obstructed by doctors and prescribers who attempt to maintain their power in a market where low-cost third-party contact lens retailers are offering the same for a far lower price. Prescribers unabashedly employ tactics and methods that have no other purpose or design but to confuse patients and to make it more difficult for them to obtain affordable contacts elsewhere. The evidence LD Vision Group provides demonstrates that prescribers are improperly affecting the market to the detriment of consumers and low-cost retailers like LensDiscounters.com. We encourage the Commission to stem such efforts, and as far as is possible, guarantee consumers will have a free and unfettered choice, unpolluted by such tactics. We therefore ask the Commission to reconsider our recommendations and implement the following:

- Amend 16 C.F.R. Part 315.5(d) to deem any inadequate, incomplete communication by a prescriber as a failure to communicate under Section 315.5(c)(3).

## CONTACT LENS FITTINGS

LensDiscounters.com wishes to clarify its position, taken in its original comment, and concerning contact lens prescription renewals. *See* LD Comment 5. The Commission appears to have misunderstood our position, failing to appreciate the context within which it was stated. The Commission states that LD Vision Group "declared that while it generally makes sense for patients to undergo a comprehensive eye examination to ensure good health, patients should not have to undergo a follow-up contact lens fitting after receiving a trial pair of contact lenses from a prescriber." NPR at 92–93. However, our comments were made while discussing issues related specifically to the prescription ***verification*** process for replacement contact lenses. LensDiscounters.com has experienced prescribers refusing to validate a prescription until after a consumer attends an unnecessary contact refitting; while others properly validate and verify a prescription after an "initial fitting" and following annual or follow-up eye exams. If the eye care provider has already conducted its eye exam, prescribed lens parameters for a patient, and have ensured the prescription properly fits at an "initial fitting," then barring specific medical concerns, other prescription-related services, such as an additional or subsequent contact lens fitting, are unnecessary. A patient, after her "initial fitting," is aware and competent to order contacts from any contact retailer she wishes and should not be obstructed or coerced into a sale by the prescriber. Prescribers obstruct patient purchases from low-cost retailers, such as LensDiscounters.com, by claiming that prescription release "requirements," which are unnecessary to protect a patient's eye health, have not been met by the patient. *See* LD Comment 5, n.3. In the replacement contact lens market, after the prescription expires, it is unclear from the rule what consumers must do to obtain a renewal prescription. Some prescribers simply require consumers to undergo a new eye-health exam, others require consumers to undergo an unnecessary contact lens fitting, while still others require consumers do both before they are able to purchase replacement lenses from low-cost contact retailers like LensDiscounters.com. *Id.*

The issue that LensDiscounters.com raised in this context is important because it asks the Commission to make clear, under the rule, when an initial or renewal prescription becomes active, or when the consumer has the right to exercise her unfettered choice to purchase contact lenses from any retailer. There is currently no definitive marker under the rule determining exactly when a consumer's right to purchase contacts from a third party is established. Our comment highlights LensDiscounters.com's experience that prescribers are interpreting their obligations under the rule in inconsistent and anticompetitive ways. Some consumers are allowed to purchase replacement contacts after an eye exam, while others are not permitted until after a fitting by the doctor/prescriber occurs. *Id.* The current rule fails to clearly articulate when a contact lens prescription becomes active. It does not definitively guide prescribers to a common standard of action for releasing and verifying contact lens prescriptions. Without an amendment addressing these

deficiencies, prescribers will capitalize on opportunities to thwart the rule's intended effect and purpose.[2]

Further, while the Commission offers its acknowledgement form to address anticompetitive concerns, it does not go sufficiently far enough to cure the issues LensDiscounters.com experiences and raised in its comments. The proposed form the Commission has suggested, an acknowledgement that the prescription has been released to the patient, would do nothing to change the obstruction a patient faces when attempting to purchase from low-cost retailers. The prescriber's purpose for implementing unnecessary release requirements is to get patients to come into the prescriber's office so they can coerce sales. The Commission's form would require patients to come to the prescriber, on the prescriber's terms, to sign the acknowledgement. This creates inefficiencies for the market and inconveniences the consumer in the same manner as we've previously mentioned. As a more effective and efficient alternative, we propose the Commission adopt a waiver form, which closely follows the substantive content provided in **Exhibit E**. LensDiscounters.com requests the Commission reconsider our recommendations and implement the following:

- Amend 16 C.F.R. Part 315.3(b) to prohibit a prescriber from requiring more than an eye-health examination for a contact-lens prescription, ***renewal*** and release, unless the prescriber determines that additional evaluation is necessary to the ocular health of a particular patient

***and***

- Allow any patient to waive the prescription verification requirement after an eye exam is conducted by confirming with the seller that they (a) are aware of the risks associated with the improper use of contact lenses and (b) are aware that it is recommended that a patient receive an eye examination every year. *See* **Exhibit E** for example of proposed acknowledgement and waiver.

## PRIVATE LABELS—ISSUES

Summarizing the issues related to private label prescriptions, the Commission, noting LD Vision Group's concerns, stated that LD Vision Group did not "quantify the extent" of the problem, or "provide empirical evidence" as to its scope. *See* NPR at 114. The Commission further expressed its understanding that sales of private label lenses "comprise a small part of the market, and most major manufacturers do not sell private label lenses." *Id.* For those reasons, the Commission decided to not implement any of LD Vision Group's recommendations. *Id.* at 115. In responding to the Commission, LD Vision Group here supplements information previously provided, demonstrating instances where rule violations occurred in relation to private label prescription improperly written and/or without equivalents.

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2 As an example—before following up to a contact lens fitting, a patient could receive an eyeglass prescription and assume it's complete for contacts.

LensDiscounters.com highlights for the Commission a well-known canon of medical ethics—"[p]hysicians should not participate in exclusive distributorships of health-related products which are available only through physician's offices. Physicians should ***encourage*** manufacturers to make products of established benefit more widely accessible to patients than exclusive distribution mechanisms will allow." *The American Medical Association Code of Ethics*, 8.063 Section 4. While the rule seeks to achieve what Section 8.063 articulates, we find that doctors/prescribers all too often act in ways that support, and in some instances attempt to create, what is strictly forbidden, exclusive distributorships. A doctor's convoluted prescribing of private label contacts to consumers, which is a blatant failure to provide proper equivalents in violation of the rule, effectively creates this exclusive distributorship.

Contact lens manufacturers themselves are all too eager to serve as accomplices for the prescriber to achieve these forbidden schemes. LensDiscounters.com attaches **Exhibit D** as an example to show how manufacturers work in tandem with prescribers to effectively produce exclusive distributorship. The independent and combined actions the prescriber and manufacturer take, together work to misinform and confuse the consumer, while intimidating low-cost retailers like LensDiscounters.com to not advertise or sell equivalents. These relationships and the anticompetitive effects they produce clearly undermine the rule and the market's integrity.

LensDiscounters.com disagrees with the Commission's diminishment of the private label concern because it may "comprise a small part of the market, and most major manufacturers do not sell private label lenses." *Id.*[3] This issue goes beyond the

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3 Writing prescriptions containing the equivalents between national-brand and private label contacts is a requirement under the FCLCA, and is often not done by prescribers. The Commission's characterization that the harm caused by such omissions are insignificant is misinformed, and LensDiscounters.com offers the Commission the following to consider:

(1) Luxottica is the largest retailer in the United States owning some 852 LensCrafters locations which have started carrying the "LensCrafters 1-Day Flat Pack" which is the private label to Miru 1-Day Flat Pack lenses manufactured by Menicon. They also carry "LensCrafters 1-Day Premium" which is a private label for MyDay lenses by CooperVision. Optometrists affiliated with LensCrafters also write prescriptions for these products under the name "Love Eyes Flat Pack" and "Love Eyes 1-Day Premium." *See* https://www.lenscrafters.com/lc-us/daily-disposable-contact-lenses; *see also* http://www.visionmonday.com/vm-reports/top-50-retailers/article/snapshots-of-opticals-10-largest-us-retail-players-2016/.

(2) Vision Source is the second-largest optical retailer in the United States according to Vision Monday's report "Top 50 Retailers." It uses AquaClear private labels of CooperVision's Biofinity lenses, AquaClear100 as a private label for Avaira by CooperVision, and "Fresh Day" is a private label for Clariti lenses manufactured by Sauflon (now owned by CooperVision). Vision Source uses its "unsurpassed buying power" to purchase these private label lenses at a lesser cost than the national brand equivalent. *See* http://visionsource.com/doctors/membership-benefits/unsurpassed-buying-power/; *see also* http://www.visionmonday.com/vm-reports/top-50-retailers/article/snapshots-of-opticals-10-largest-us-retail-players-2016/ (stating "The group has over 4,000 members." "The group

proportional market effect private labels have in comparison to the entire consumer market, which LensDiscounters.com believes is growing and significant. In this instance, a prescriber's violation of the rule is a further violation of the prescriber's ethical obligations as a doctor to his or her patients and profession. Consumer confidence that ethical, professional, and market rules are being followed is essential to a market's proper functioning. Where prescribers violate these rules and undermine consumer expectations, experience shows that consumers are coerced to make choices that do not benefit them, and wrongdoers are rewarded for their improper acts.

The Commission requested examples of violations relating to private labels for potential enforcement action. NPR at 116. The FCLCA requires that

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aligns independent optometrists for the purpose of growing their practices, lowering their cost of goods and sharing best practices to increase their profitability.").

(3) Walmart Vision Centers sell private labels. Walmart's Equate Monthly is also Bausch and Lomb PureVision 2, Equate 1-Day 90 Pack is Bausch and Lomb Soflens Daily Disposable, and Ultraflex II is CooperVision Biomedics 55 Premier. *See* http://www.visionmonday.com/vm-reports/top-50-retailers/article/snapshots-of-opticals-10-largest-us-retail-players-2016/ (stating "[w]ith approximately 3,000 of its own Walmart Vision Centers and another 582 Sam's Club optical locations").

(4) America's Best Contacts and Eyeglasses, a division of the fourth-largest retailer in the United States, National Vision, and sells private labels. America's Best Sofmed 55 is CooperVision Biomedics 55 Premier. *See* http://www.visionmonday.com/vm-reports/top-50-retailers/article/snapshots-of-opticals-10-largest-us-retail-players-2016/.

(5) Costco Optical is the fifth-largest retailer in the US and sells private labels. Kirkland Signature Premium 1-Day lenses is CooperVision MyDay 1-Day lenses. *See* http://www.visionmonday.com/vm-reports/top-50-retailers/article/snapshots-of-opticals-10-largest-us-retail-players-2016/ ("Costco Wholesale operated 475 Costco Optical vision centers in 492 locations in the US and Puerto Rico for 2015").

(6) Visionworks operates 699 locations in the United States and sells private labels. We outlined in our original comment the confusing identifiers that this prescriber/retailer uses in our original comment. *See* LD Comment 7; https://www.visionworkscontacts.com/Lenses/Brands/AquaTech; http://www.visionmonday.com/vm-reports/top-50-retailers/article/snapshots-of-opticals-10-largest-us-retail-players-2016/.

In addition to the above prescriber/retailers that sell private labels, many other practices that do not have their own private brand typically sell "limited distribution" private labels; one being CooperVision's Encore Premium label, which is labeled with an 8.6 base curve, whereas the identical national brand equivalent Frequency 55 Aspheric is labeled as 8.7.

The above information challenges the Commission's fundamental assumptions about the size of the private label market and the extent that violations of the rule related to private labels have in undermining and frustrating its purposes. LensDiscounters.com strongly encourages the Commission to revisit its understanding of the private label market, and find that prescribers/retailers utilize the imprecision of the rule to take advantage of consumers and obstruct a substantial, not a "small" part, of the market for contact lenses.

prescriptions "contain[] sufficient information for the complete and accurate filling of a prescription, including . . . [i]n the case of a private label contact lens, name of manufacturer, trade name of private label brand, and, if applicable, trade name of equivalent brand name." 15 U.S.C. 7610(3)(H). LensDiscounters.com provides, in **Exhibit C**, specific examples of what it often experiences in its own practice, demonstrating the growing abuse by prescribers when prescribing consumers private labels and failing to provide equivalents as required under the law. Moreover, LensDiscounters.com illustrates the tenacity of these providers by attaching correspondence from Vision Source, the second largest optical retailer in the United States, threatening legal action against LensDiscounters.com for providing private label equivalent information on its website to assist consumers with exercising their rights to purchase the national brand. **Exhibit D**. Vision Source is an association of independent optometrists who have commissioned their own private labels from CooperVision in an attempt to recapture the rents they have lost to the Contact Lens Rule and the FCLCA.

LensDiscounters.com provides the following annotations to Exhibits C and D:

| Ex. Pages | Comment |
|---|---|
| C-1 | This prescription abbreviates the private label "Sofmed Breathables XW" to SMBXW which is not the correct trade name of the private label brand. It does however note the equivalent label in the "substitution permissible" section. |
| C-2–C-3 | This prescription written by a Vision Source doctor indicates Aqua Clear lenses, but not the national-brand equivalent which is Biofinity by CooperVision. It also does not list the name of the manufacturer. |
| C-4 | The equivalent trade name "Biofinity" is not listed. |
| C-5 | This doctor, affiliated with the USA's largest optical retailer LensCrafters, a division of Luxottica Retail, has issued a prescription for "Love Eyes LC 1-Day Premium" which is a private label for CooperVision's MyDay lenses. It does not name the manufacturer on the prescription. |
| C-6 | The trade names of the product and manufacturers are not named in full (they are abbreviated or in short-form). The national brand of Ultraflex II Aspheric is not indicated (Biomedics 55 Premier by CooperVision). |
| C-7 | The equivalent trade name of Biomedics Toric is not listed. |
| C-8 | The equivalent trade name "Biofinity" is not listed. |
| C-9 | This prescription does not mention the national-brand equivalent Biofinity. It does not name the manufacturer. |
| C-10–11 | This doctor wrote a prescription for AquaClear and AquaClear Toric without noting the trade name of the equivalent brand name; Biofinity. The doctor is indicating the AquaClear Toric BC of 8.7 should be an 8.6, however it is not available in 8.6. As well, it does not name the manufacturer. |
| C-12 | The equivalent trade name "Biofinity" is not listed. The name of the manufacturer is not listed. |
| C-13 | This Vision Works doctor did not list the trade name of the equivalent brand name. |
| C-14 | The doctor did not name the equivalent trade name of Biofinity Toric. |
| C-15 | The doctor did not name the equivalent trade name of Biofinity Toric. |

| Ex. Pages | Comment |
|---|---|
| C-16 | This Vision Works doctor indicates the lenses' equivalent trade name of Biofinity Toric in the "notes" which arguably adheres to the rule. Our comment on this example is that it should actually state that "Biofinity Toric" is the equivalent. |
| C-17 | This doctor did not list the trade name of the equivalent brand name. |
| D | Correspondence between counsel for Vision Source and counsel for LensDiscounters.com in which Vision Source seeks to prevent LensDiscounters.com from educating consumers about private label equivalents through a frivolous threat of Lanham Act litigation. |

In light of this supplementation, LensDiscounters.com requests the Commission reconsider its rejection of our recommendations, and suggests the following actions be taken:

- Amend 16 C.F.R. Part 315 to require prescribers to annotate a private-label lens prescription with the brand-name equivalent. If a name-brand equivalent is unavailable, the private-label prescription must be medically necessary for that particular patient;

***and***

- Amend 16 C.F.R. Part 315 to require manufacturers of contact lenses to make brand equivalency information available to all sellers, consumers, and the FTC;

***or***

- [Updated] Amend 16 C.F.R. Part 315 to require manufacturers and retailers to make brand equivalency information available and easily accessible for private-labels on their brand label packaging and online.

## CONCLUSION

Resolving these issues are essential to guarantee consumers have an uncoerced and unfettered choice in a free market. The Commission should take all appropriate actions to prevent either manufacturers or prescribers from hindering, confusing, or frustrating consumers in their decision to purchase contacts from low-cost retailers like LensDiscounters.com. These are issues affecting consumers ***today***. LensDiscounters.com encourages the Commission to exercise foresight by addressing the shortcomings in the rule that prescribers exploit to frustrate its purpose during this review—these issues cannot wait for the next periodic review of the rule.