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## REGULATORY PROTECTIONISM IN THE CONTACT LENS MARKET

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### INTRODUCTION

New technologies often present competitive threats to established industries. Incumbent businesses sometimes respond in turn by seeking to use the political process to limit market access to these emerging threats or to regulate alternative business models out of existence. The costs imposed by these interventions, which are borne largely by consumers, are examples of what economists call “rent-seeking.”<sup>1</sup> The market for corrective contact lenses provides a case study in this form of political exploitation.

According to public choice theory, rents typically are extracted from a large number of consumers, but flow to a small percentage of market actors. As a result of this dynamic of “concentrated benefits, diffuse costs,” these rents often may go undetected until they are exposed by an event that disrupts

1. Daniel A. Crane, “Tesla, Dealer Franchise Laws, and the Politics of Crony Capitalism,” *Iowa Law Review*, 101, no. 2: 573-607, 2016. <http://repository.law.umich.edu/cgi/viewcontent.cgi?article=2720&context=articles>

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an industry.<sup>2</sup> In the retail market for contact lenses, once monopolized entirely by physicians, this moment arrived with the advent of e-commerce. From the mid-1990s onward, health-care providers saw continuing declines in lens-wear sales as the internet proved itself an attractive marketplace to buy and sell contact lenses.

Over the past two decades, the struggle for market share within the contact-lens industry has spilled into the legal, legislative and regulatory arenas. This policy study offers a brief historical overview of recent efforts to grant consumers greater freedom in the contact-lens market, as well as legislative and regulatory pushback by eye-care providers to curtail those reforms.

### REGULATORY LANDSCAPE

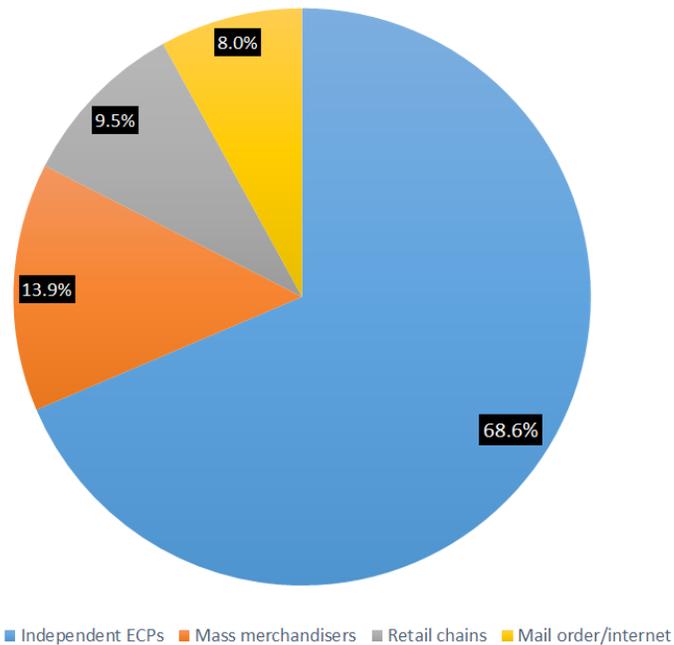
Starting in the early 1990s, eye-care providers’ initial response to the competitive threat posed by outside retailers was to enforce a “doctors-only” distribution policy, in collusion with major lens-wear manufacturers. According to a lawsuit filed in 1994 by 32 state attorneys general against the American Optometric Association—the profession’s largest trade association—the AOA colluded with lens-wear makers to ensure their products were distributed exclusively through licensed optometrists and ophthalmologists, eschewing online and mail-order retailers. The antitrust suit eventually was settled in 2001,<sup>3</sup> with some individual states settling earlier.

Even subsequent to the settlement, manufacturers continued to market some products exclusively to doctors through trade advertisements that touted their ability to restrict competition. A mid-2000s brochure for Hydrogel Vision Corp.’s Extreme H2O lenses promised doctors “a lens that cannot

2. James D. Gwartney and Richard E. Wagner, “Public Choice and the Conduct of Representative Government,” *Public Choice and Constitution Economics*, JAI Press, pp. 3-28, 1988. <http://mason.gmu.edu/~atabarro/Gwartney%20Wagner%201988.pdf>

3. *Primary Care Optometry News*, “AOA settles contact lens antitrust lawsuit,” June 2001. <http://www.healio.com/optometry/contact-lenses-eye-wear/news/print/primary-care-optometry-news/%7Ba8b8eb30-c7c0-4492-8e9b-aa7cfde6f4fb%7D/aoa-settles-contact-lens-antitrust-lawsuit>

FIGURE I: CONTACT LENS MARKET SHARE BY RETAIL CHANNEL, 2003



SOURCE: Federal Trade Commission

be shopped around.”<sup>4</sup> A contemporary ad for CooperVision’s ProClear Compatibles noted that they were “only available through your practice,” allowing ECPs to enjoy “increased patient loyalty and greater profitability.”<sup>5</sup>

Nonetheless, when the doctors-only marketing scheme was exposed in court, eye-care providers (ECPs)<sup>6</sup> largely were forced to find other ways to offset online retailers’ market penetration. Doctors began to leverage the most important tool over which they retained control: the prescription-verification process. As noted by the Federal Trade Commission, ECPs intentionally neglected to provide patients with copies of their prescriptions, thus steering them to purchase contact lenses in-office at higher prices.<sup>7</sup>

In 2003, Congress passed the Fairness to Contact Lens Consumers Act,<sup>8</sup> legislation intended to extend to contact-lens wearers rights that commonly had been granted to eyeglass wearers for more than a quarter-century, including the right to obtain a copy of one’s prescription and to shop around. At the time, only 22 states required that prescribers release prescriptions to contact-lens patients.

The consumer protections ultimately were finalized in July 2004, when the FTC promulgated the “Contact Lens Rule,”<sup>9</sup> which lifted anticompetitive barriers by enacting the following policies:

- Prescribers may not charge fees for writing lens prescriptions;
- Patients cannot be instructed to sign a waiver before the prescription is released;
- Eye-care patients are not obligated to purchase lenses in-office following an eye exam; and
- Outside retailers can verify prescriptions passively when the prescriber fails to communicate with the seller within eight business hours of receiving a verification request.

4. Jennifer Byrne, “Pending legislation will amend the contact lens fairness act,” Primary Care Optometry News, November 2006. <http://www.healio.com/optometry/regulatory-legislative/news/print/primary-care-optometry-news/%7Bc23f9f6e-20fa-4c26-a31b-6d5d3f2d0961%7D/pending-legislation-will-amend-the-contact-lens-fairness-act>

5. Testimony of Jonathan Coon, “Hearing before the Subcommittee on Commerce, Trade and Consumer Protection of the House Energy & Commerce Committee,” Sept. 15, 2006. <http://archives.republicans.energycommerce.house.gov/108/hearings/09152006Hearing2023/Coon.pdf>

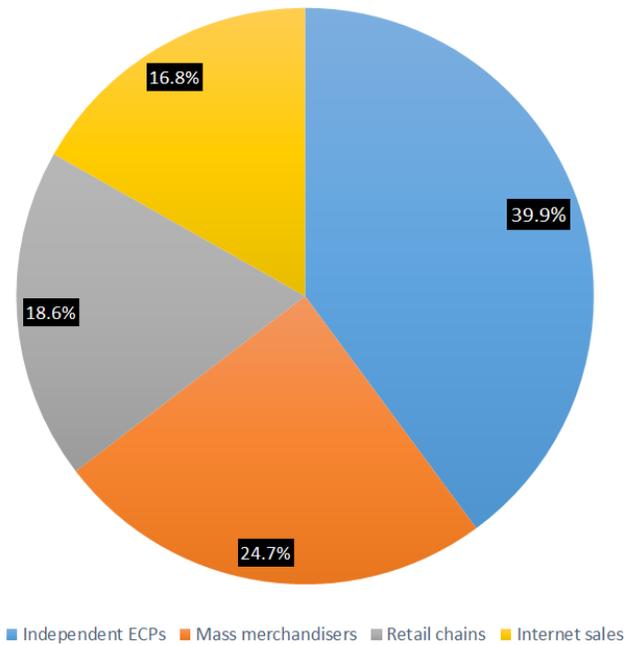
6. For this report’s purposes, an “eye care provider” (ECP) is defined as the office of any health-care professional who has the ability to conduct eye exams and/or prescribe contact lenses.

7. Staff of the Federal Trade Commission, “Possible Anticompetitive Barriers to E-Commerce: Contact Lenses,” March 2004. [https://www.ftc.gov/sites/default/files/documents/advocacy\\_documents/possible-anticompetitive-barriers-e-commerce-contact-lenses-report-staff-ftc/040329clreportfinal.pdf](https://www.ftc.gov/sites/default/files/documents/advocacy_documents/possible-anticompetitive-barriers-e-commerce-contact-lenses-report-staff-ftc/040329clreportfinal.pdf)

8. 108<sup>th</sup> Congress, Public Law 108-164, Dec. 6, 2003. <https://www.congress.gov/108/plaws/publ164/PLAW-108publ164.pdf>

9. Federal Trade Commission, “Contact Lens Rule; Ophthalmic Practice Rules; Proposed Rule and Final Rule,” *Federal Register*, Vol. 69, No. 23, Feb. 4, 2004. [https://www.ftc.gov/sites/default/files/documents/federal\\_register\\_notices/contact-lens-rule-ophthalmic-practice-rules-16-cfr-parts-315-and-456/040204contactlensrule.pdf](https://www.ftc.gov/sites/default/files/documents/federal_register_notices/contact-lens-rule-ophthalmic-practice-rules-16-cfr-parts-315-and-456/040204contactlensrule.pdf)

FIGURE 2: CONTACT LENS MARKET SHARE BY RETAIL CHANNEL, 2014



SOURCE: Federal Trade Commission

At the time of its introduction, the Contact Lens Rule was considered effective in achieving the goal of opening the lens-wear market, which experienced rapid growth over the following decade. Annual market analyses published by *Contact Lens Spectrum* show that the number of contact-lens wearers over age 18 grew from 36 million in 2005<sup>10</sup> to 40.9 million in 2015.<sup>11</sup> Concurrently, the U.S. industry’s market valuation grew from an estimated \$1.8 billion in 2005 to \$2.7 billion in 2015.

At the same time, as demonstrated in Figure 1 and Figure 2, the market share enjoyed by independent ECPs shrunk from 68.6 percent before the Contact Lens Rule to 39.9 percent in 2014. By contrast, the market share of mass merchandisers grew from 13.9 percent to 24.7 percent; the market share of retail chains grew from 9.5 percent to 18.6 percent; and the market share of internet sales grew from 8.0 percent to 16.8 percent.

However, this shift to a more competitive market has been threatened by a growing trend of ECPs falsely denying prescription requests made through the “passive verification process.” The FTC’s Contact Lens Rule requires that, when a patient orders lenses through an outside retailer, the prescription is considered verified if the ECP fails to communicate with the seller within eight business hours of receiving

the seller-provided verification information. There is evidence that some prescribers intentionally fail to provide the consumer’s complete prescription to third-party sellers. In April 2016, the FTC issued 55 warning letters—45 sent to prescribers and 10 issued to retailers—regarding alleged violations of the Contact Lens Rule’s verification clause.<sup>12</sup> The commission simultaneously published guidance for ECPs emphasizing that a prescription must be provided even if the patient doesn’t request it.<sup>13</sup>

Under amendments to the Contact Lens Rule that the FTC proposed in December 2016—following a comment period that began in September 2015 as part of a once-per-decade systematic review of all FTC rules—doctors would, in addition to providing patients copies of their contact-lens prescriptions, have to present the patient an acknowledgment form certifying that patient understands he or she is “free to purchase contact lenses from the seller of my choice.” Prescribers would have to maintain the signed acknowledgments on file for up to three years, and to note any instances in which a patient refuses to sign the acknowledgment.<sup>14</sup>

10. Joseph T. Barr, “Contact Lenses 2005,” *Contact Lens Spectrum*, Jan 1, 2006. <http://www.clspectrum.com/articleviewer.aspx?articleID=12913>

11. Jason J. Nichols, “Contact Lenses 2015,” *Contact Lens Spectrum*, Jan. 1, 2016. <http://www.clspectrum.com/articleviewer.aspx?articleID=113689>

12. Mary K. Engle, “Notice of the Fairness to Contact Lens Consumers Act and the Contact Lens Rule,” Federal Trade Commission, April 2016. [https://www.ftc.gov/system/files/attachments/press-releases/ftc-issues-warning-letters-regarding-agencys-contact-lens-rule/160407modelwarningletter\\_prescribers.pdf](https://www.ftc.gov/system/files/attachments/press-releases/ftc-issues-warning-letters-regarding-agencys-contact-lens-rule/160407modelwarningletter_prescribers.pdf)

13. Press release, “FTC Issues Warning Letters Regarding the Agency’s Contact Lens Rule,” Federal Trade Commission, April 7, 2016. <https://www.ftc.gov/news-events/press-releases/2016/04/ftc-issues-warning-letters-regarding-agencys-contact-lens-rule>

14. Federal Trade Commission, “16 CFR Part 315, RIN 3084-AB36, Contact Lens Rule,” Federal Register, Dec. 7, 2016. [https://www.ftc.gov/system/files/documents/federal\\_register\\_notices/2016/12/contact\\_lens\\_rule\\_published\\_frn12716.pdf](https://www.ftc.gov/system/files/documents/federal_register_notices/2016/12/contact_lens_rule_published_frn12716.pdf)

Another provision of the proposed amendments would allow sellers to substitute identical contact lenses manufactured by the same company specified on a prescription, but sold under a different label. The proposed rule also affirmed the validity of the passive-verification process, upheld the use of automated telephone verification systems and, as discussed in the next section, sought to dispel false health claims spread by some ECPs.

## MISLEADING HEALTH CLAIMS

In making the case for regulatory interventions that preserve their incumbent business model, ECPs long have cited claims that distribution of contact lenses by alternative vendors poses health concerns for consumers. As former Connecticut Attorney General Richard Blumenthal noted in bringing a multi-state antitrust case against the AOA and CIBA Vision Corp. during the 1990s: “The industry has hidden behind claims of health concerns requiring that individuals get their contact lenses from certain professionals. ... But there is no scientific basis to that claim.”<sup>15</sup>

More recently, those seeking stricter oversight of online sales have tended to cite an August 2015 survey from the Centers for Disease Control and Prevention finding that “approximately 99 percent of wearers reported at least one contact lens hygiene risk behavior.”<sup>16</sup> The survey was conducted in collaboration with Contact Lens Assessment in Youth (CLAY), a group of university researchers with financial support from the American Academy of Optometry and the American Optometric Association. In its December 2016 notice of rulemaking, the FTC offered caveats about the CDC survey’s topline claim that nearly all lens wearers practiced poor hygiene, and particularly the use of that finding as justification for restrictions on online sales:

First, the authors reached this number by including any wearer that indicated that they had ‘ever’ engaged in a risk behavior. Hence, the 99 percent figure includes every wearer, who at any time, had engaged in a risk behavior even once. Second, the survey instrument asked users where they purchased their lenses, and in a separate article, the authors did not conclude that there was any difference in either habits or health risks based on whether the lenses were purchased from a provider, retail store without an exam, or over the internet.<sup>17</sup>

15. Richard Blumenthal, “Blumenthal Files Lawsuit against Three Contact Lens Manufacturers, Optometrists Association,” Office of the Connecticut Attorney General, Dec. 19, 1996. <http://www.ct.gov/ag/cwp/view.asp?A=1772&Q=282426>

16. Press release, “Nearly all contact lens wearers in national survey report risky eye care behaviors that can lead to eye infections,” Centers for Disease Control and Prevention, Aug. 20, 2015. <https://www.cdc.gov/media/releases/2015/p0820-contact-lens.html>

17. FTC, 2016.

A separate CLAY group study from 2015 purported to test how proximity to a patient’s prescriber correlated with soft-contact-lens wear-and-care practices,<sup>18</sup> with results later published in *Contact Lens Journal* in December 2016.<sup>19</sup> Notably, the study found that purchasing location had only limited association with eye-health risks. Purchasing contacts in-office did not improve hygiene habits, nor did it reduce behavior that puts the wearer at risk for infection or inflammation. Of the 968 lens wearers surveyed, 646 (66.7 percent) purchased contacts directly through their eye-care provider; 104 (10.7 percent) through a contact-lens retailer; and 218 (22.6 percent) study participants purchased them on the internet. The survey revealed that all three groups were equally likely to wear soft contact lens overnight, to “top off” old contact lenses with new solution or to expose lenses to tap water.

Moreover, a 2014 study published in *Eye & Contact Lens*<sup>20</sup> found that regulations on contact-lens retailers also had only limited correlation with health risks. Researchers reviewed cases of eye-health complications associated with contact lenses from unregulated sources of supply, and identified hygiene habits as the main cause of health complications. In 12 of the 70 cases studied (17 percent), contact lenses were borrowed from or shared with another lens wearer. But in only four of the cases (6 percent) were the contact lenses obtained over the internet. In most of those cases, the patient waited several weeks to address the concern with a health-care provider.

In a submission to the FTC during the commission’s open comment period on the Contact Lens Rule, the AOA argued that online purchasers are at a higher risk of developing microbial keratitis or other complications, as found most notably in a 2012 study by Fiona Stapleton.<sup>21</sup> Among the other studies AOA cited was a 2008 article by Joshua Fogel and Chaya Zidile in the journal *Optometry* finding that patients who purchased contact lenses at a doctor’s office more often adhered to certain Food and Drug Administration safety recommendations than those who purchased contact lenses at a

18. Robin Chalmers, et al., “Is Purchasing Lenses from the Prescriber Associated with Better Soft Lens Wearers’ Habits?” American Academy of Optometry, Oct. 9, 2015. <http://www.aaopt.org/purchasing-lenses-prescriber-associated-better-soft-lens-wearers-habits>

19. Robin Chalmers, et al., “Is purchasing lenses from the prescriber associated with better habits among soft contact lens wearers?” *Contact Lens & Anterior Eye*, Vol. 39, Issue 6, pp. 435-441, December 2016. [http://www.contactlensjournal.com/article/S1367-0484\(16\)30079-0/pdf](http://www.contactlensjournal.com/article/S1367-0484(16)30079-0/pdf)

20. Graeme M. Young, Alex G. Young and Carol Lakkis, “Review of Complications Associated With Contact Lenses From Unregulated Sources of Supply,” *Eye & Contact Lens: Science & Clinical Practice*, Vol. 40, Issue 1, pp. 58-64, January 2014. <http://journals.lww.com/claoptjournal/pages/articleviewer.aspx?year=2014&issue=01000&article=00011&type=abstract>

21. Fiona Stapleton, et al., “Risk factors for moderate and severe microbial keratitis in daily wear contact lens users,” *Ophthalmology*, 119:1516-1521, 2012. <https://www.ncbi.nlm.nih.gov/pubmed/22521083>

store or over the internet.<sup>22</sup> The AOA also cited a 2010 study from Yvonne Wu and researchers at the British Contact Lens Association that identified poor-hand hygiene, inadequate lens care and not remembering when to come back for check-ups as the most common problems among lens wearers, while also finding an association between buying lenses over the internet and forgetting to come back for check-ups.<sup>23</sup>

For its part, the FTC reviewed the studies in question and determined they did not “reliably demonstrate that purchasing lenses online is a risk factor, or that online purchasers are at a higher risk of developing microbial keratitis or any other ocular complication.” As the commission stated:

The Fogel and Wu studies have relatively small samples of consumers who purchased contact lenses over the internet and the sample recruiting methodologies call into question whether the results are generalizable to the national population...The Stapleton study identified internet/ mail order purchases as a potential risk factor for microbial keratitis in a large sample from Australia. However, when the authors of the Stapleton study limit their sample to cases of moderate to severe keratitis, internet/mail order purchases are not found to be a risk factor.<sup>24</sup>

Ultimately, the FTC’s proposed amendments to the Contact Lens Rule rejected the AOA’s objection that the existing rule failed to address potential health concerns adequately.

## PROTECTIONIST LEGISLATION

Despite the FTC’s findings, eye-care providers and others in the medical lobby have continued an ongoing fight in Congress to tighten restrictions on online and independent retailers of contact lenses, with particular focus on constraining passive verification. In the 114<sup>th</sup> Congress, this effort came in the form of the Contact Lens Consumer Health Protection Act, introduced in the Senate in April 2016 as S. 2777 and in the House in September 2016 as H.R. 6157.

The bills would amend the Fairness to Contact Lens Consumers Act by gutting the passive verification process. Rather than a prescription being considered verified if the prescriber fails to communicate within eight business hours, the measure would require that a prescription be considered unverified until the seller obtains affirmative confirmation of the accuracy of the prescription in any instance in

which a prescriber communicates a question or concern. It also would require contact-lens sellers to provide a toll-free telephone number and email address for prescribers to use to communicate such questions and sets penalties of up to \$40,000 per violation for any seller that fails to comply with the verification process.

The measure also would repeal the Federal Trade Commission’s authority to adjust the eight-hour passive verification period and calls for a study by the Centers for Disease Control and Prevention on potentially negative health effects of seller violations.<sup>25</sup>

Most concerning to independent retailers, the bill would permit prescribers to issue written notification to sellers requesting a specific method of contact for verification requests—such as fax or website form, in addition to telephone and email—which the seller must keep on file for a period of no less than three years. This would provide ECPs a loophole allowing them to deny or delay a seller’s request more easily and to halt passive verification, while the database could prove an increasingly large paperwork burden as e-commerce volume continues to grow.

In requiring retailers to use a live toll-free number, the bill places a ban on automated calls, also known as “robocalls,” as a mechanism to verify prescription information. The Federal Trade Commission has, to date, declined to prohibit automated verification calls. In its December 2016 proposed rules, the commission noted that, despite receiving complaints about such calls from prescribers, “commenters did not provide any empirical data regarding the frequency of these various practices, average or aggregate costs associated with automated calls in particular, or the number of illegal or otherwise deficient contact lens sales that result from such calls.”<sup>26</sup>

The 114<sup>th</sup> Congress concluded having taken no action on the Contact Lens Consumer Health Protection Act, which failed to move out of committee in either chamber. The Financial Services and General Government Appropriations Act passed by the House in July 2016 included a committee report that urged the FTC, as part of its review of the Contact Lens Rule, “to make modifications to the rule that prioritize patient safety and strengthen enforcement mechanisms.”<sup>27</sup> An even stronger statement was included in the committee report accompanying the Senate’s version of the financial services appropriations bill. It encouraged:

22. Joshua Fogel and Chaya Zidile, “Contact lenses purchased over the Internet place individuals potentially at risk for harmful eye care practices,” *Optometry*, 79.1, pp. 23–35, 2008. <https://www.ncbi.nlm.nih.gov/pubmed/18156093>

23. Yvonne Wu et al., “Contact lens user profile, attitudes and level of compliance to lens care,” *Contact Lens Anterior Eye*, 33:183–188, 2010. <https://www.ncbi.nlm.nih.gov/pubmed/20227903>

24. FTC, 2016.

25. 114<sup>th</sup> Congress, S. 2777, Contact Lens Consumer Health Protection Act of 2016, April 11, 2016. <https://www.congress.gov/114/bills/s/2777/BILLS-114s2777is.pdf>

26. FTC, 2016.

27. 114<sup>th</sup> Congress, H.R. 5485, H. Rept. 114-624 - Financial Services and General Government Appropriations Act, 2017, June 15, 2016. <https://www.congress.gov/congressional-report/114th-congress/house-report/624/1>

...the agency to consider modifications that prioritize patient safety and strengthen enforcement mechanisms aimed at combating illegal sales of contact lenses based on expired or non-existent prescriptions, while coordinating with the CDC to disseminate contact lens safety information to consumers.

Neither the House nor Senate versions of the financial services appropriations bill cleared the Senate floor in 2016. Sponsors of the Contact Lens Consumer Health Protection Act are expected to reintroduce their legislation in the 115th Congress.

## CONCLUSION

The contact lens market serves as a microcosm of the regulatory impediments that continue to face online medical retailers. As health solutions increasingly become available online, it is imperative that lawmakers and regulators do not stifle progress and innovation.

Although special interest groups were unable to pass legislation in the 114<sup>th</sup> Congress that would carve loopholes into hard-earned consumer reforms, contact-lens wearers should remain leery of efforts by the new Congress to enact their agenda. In approaching this issue, policymakers should embrace online markets and be wary of misleading public safety arguments and efforts to impose protectionism through fear, uncertainty and doubt. Any risk posed by more vibrant online markets for contact lenses is far outweighed by their economic benefits and the access they now grant to rural, low-income and disabled communities.

## ABOUT THE AUTHORS

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