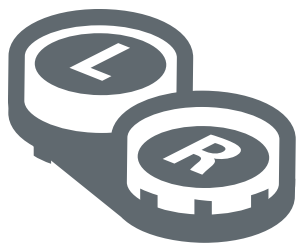


Help Make Prescription Verification Simpler and Safer for Contact Lens Patients

Co-sponsor H.R. 2748/S. 4083, the Contact Lens Prescription Verification Modernization Act

Reps. Michael Burgess, M.D., R-Texas, and Lisa Blunt Rochester, D-Del., and Sens. Tammy Duckworth (D-Ill.), and Sen. John Boozman (R-Ark.), introduced the bipartisan Contact Lens Prescription Verification Modernization Act (H.R. 2748/S. 4083) **to help make the contact lens prescription verification process simpler and safer for millions of Americans.**



45 million
Americans choose contact lenses for their vision correction needs.

Contact lenses have long been recognized in law and regulation as medical devices. Today, roughly 45 million Americans choose contact lenses for their vision correction needs. All contact lenses, even cosmetic ones, require a prescription and must be properly fitted and prescribed by a doctor of optometry or other eye doctor (ophthalmologist) following an eye health and vision exam to determine a patient's suitability for contact lens wear.

Although contact lenses are safe and effective, their **improper use or fit can lead to serious health complications**, including:

- Infections
- Corneal Edema
- Ulcers

A poor-fitting contact lens can also lead to an irreversible growth of blood vessels in the eye (corneal neovascularization), which can result in:

- Scarring
- Infections
- Blindness
- Removal of the eye due to persistent, uncontrollable pain

Summary

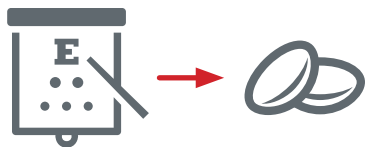
Contact lenses are a safe and popular choice for vision correction. Because ill-fitting or improperly used contact lenses can result in serious eye and vision conditions, the FDA regulates contact lenses as Class II and Class III medical devices, which require an eye doctor's prescription and oversight. Both the FDA and the CDC inform patients that contact lenses are not "one-size-fits-all" devices and that regularly scheduled comprehensive eye exams are critical to ensuring optimal eye health.

Through the Fairness to Contact Lens Consumers Act (FCLCA), Congress charged the FTC with enforcing contact lens prescription verification requirements. However, lax FTC enforcement of unscrupulous online contact lens sellers and the continued use of problematic verification robocalls has led to a growth in illegal sales, including through the filling of expired or non-existent prescriptions and the filling of prescriptions with devices other than what was prescribed by the doctor.

The Health Care Alliance for Patient Safety supports the bipartisan **Contact Lens Prescription Verification Modernization Act H.R. 2748/S. 4083, to help modernize the contact lens prescription verification process and make it simpler and safer for millions of contact lens wearers.** U.S. House and Senate members are asked to co-sponsor the Contact Lens Prescription Verification Modernization Act (H.R. 2748/S. 4083).



HEALTH CARE ALLIANCE FOR
PATIENT SAFETY



The U.S. Food and Drug Administration (FDA) regulates **contact lenses as Class II and Class III medical devices, which require an eye doctor's prescription and oversight.** The FDA and the U.S. Centers for Disease Control and Prevention (CDC) inform patients that contact lenses are not "one-size-fits-all" devices and that **regularly scheduled comprehensive eye exams are critical to ensuring optimal eye health.**



Increasingly, online contact lens **sellers are using verification robocalls that are difficult to understand, do not include all of the necessary information to confirm the prescription, and create barriers for doctors to communicate back the necessary prescription corrections**—including that the request is being made for the wrong devices or for an individual who is not a patient of that doctor. Some online sellers are knowingly taking advantage of the current "passive verification" system (doctors have eight business hours to respond or the prescription is considered verified) to sell medical devices to patients not prescribed by an eye doctor—needlessly placing them at risk.

A 2016 patient survey highlighted the scale of the problem:

1 in 3

patients were able to purchase lenses using an already-expired prescription.

&

1 in 4

patients reported receiving different medical devices than those prescribed by their eye doctor.



Today, millions of contact lens wearers purchase lenses online through internet mass retailers. As a patient health safeguard, the FCLCA requires online sellers to verify the validity of contact lens prescriptions with the patient's doctor before fulfilling an order.

While the FCLCA clearly allows telephone, fax or email for verifying prescriptions, the FTC has interpreted the law to allow robocalls as well. However, the use of robocalls to confirm the accuracy of a prescription, which includes specific numbers for strength, base curve and quantity, is far too complicated for an automated phone system.

As noted by the FTC, the current regulatory environment allows bad actors to utilize a practice known as "company-driven substitution" of contact lenses, whereby patients' prescribed lenses are being replaced with alternative products, often of inferior quality, without the consumers' knowledge or consent.

Consumers deserve transparency and choice when it comes to their health care decisions, particularly when it concerns something as critical as their vision. We must work together to close loopholes in the regulatory framework and hold bad actors accountable for their actions.

Help make the prescription verification process simpler and safer for contact lens patients: **Co-sponsor the Contact Lens Prescription Verification Modernization Act (H.R. 2748/S. 4083)** To co-sponsor the Contact Lens Prescription Verification Modernization Act (H.R. 2748), please contact **Jacquelyn**

Incerto in Rep. Burgess' office at 5-7772 or Amber Ray in Rep. Blunt Rochester's office at 5-4165 or Eve Schoenberg in Sen. Duckworth's office at 4-2854 or Bailey McCue in Sen. Boozman's office at 4-4843.

The Health Care Alliance for Patient Safety (HCAPS) was founded in 2018 to advocate for patient safety and to protect and defend the doctor-patient relationship. Our members come together from across the nation to raise awareness and protect public health. Advancing policy and collaboration between leading health care advocates, vision innovators, and treatment specialists is essential to push patient care and vision protection forward.

**1505 Prince Street, Suite #300
Alexandria, VA 22314
P: 800.365.2219**



Contact Lens Prescription Verification Modernization Act (H.R. 2748) Co-sponsors*

| | |
|-------------------|--|
| Arizona | Lesko (R) |
| Arkansas | Westerman (R), Sen. Boozman (R) |
| California | Brownley (D) |
| Delaware | Blunt Rochester (D) |
| Florida | Rutherford (R) |
| Georgia | Bishop (D), Ferguson (R) |
| Illinois | Bost (R), Foster (D), Krishnamoorthi (D), Quigley (D), Ramirez (D), Schneider (D), Sen. Duckworth (D) |
| Kansas | Estes (R), LaTurner (R), Mann (R) |
| Maine | Pingree (D) |
| Nebraska | Bacon (R) |

| | |
|-----------------------|---------------------------|
| New Hampshire | Kuster (D) |
| New Jersey | Van Drew (R) |
| New York | Lawler (R), Tonko (D) |
| North Carolina | Davis (D), Nickel (D) |
| Pennsylvania | Fitzpatrick (R) |
| South Carolina | Mace (R) |
| Tennessee | Kustoff (R) |
| Texas | Burgess (R), Sessions (R) |
| Washington | Perez (D) |
| Wisconsin | Pocan (D) |
| Wyoming | Hageman (R) |

* As of 4/1/24



HEALTH CARE ALLIANCE FOR PATIENT SAFETY

FTC publication in the Federal Register shows that FTC is aware passive verification and robocalls are being used to manipulate the system, but are unwilling to take action

[Federal Register/Vol. 84, No. 102/Tuesday, May 28, 2019/Proposed Rules](#)

FTC states:

“Concerns about passive verification resulting in patients receiving contact lenses for which they have no prescription are not new, and were considered when Congress passed the FCLCA and in the NPRM in 2016. What is new, however, is the emergence of business models that rely exclusively, or almost exclusively, on passive verification as a means to substitute their own brand of daily contact lenses. Under these business models, sellers advertise directly to consumers, often through Facebook or other social media platforms, and often sell their lenses through subscription services. Several of these companies sell one type of lens only, made from a single material, with one modality, base curve, and diameter. Some consumers who have been prescribed toric lenses for astigmatism or multifocal lenses have ordered and received lenses from these sellers, unaware at the time they order that the sellers do not offer appropriate lenses for them. The only information some sellers request from consumers about their contact lens prescription is the desired power(s) of the lenses, and the websites for some do not include a mechanism for consumers to upload their actual prescription. Rather, these sellers ask consumers to provide prescriber information and represent that they will check with, or verify, the prescription with the prescriber. Sellers may then contact the prescriber with a verification request that includes the power of the consumer’s lenses, but substitutes the seller-manufacturer’s name as the brand of lens. Should a prescriber fail to invalidate such a verification request within eight business hours (as dictated by the Rule), the seller may believe it is authorized to ship that month’s lenses, and subsequent subscription orders for a year or two, depending on state prescription expiration limits. The Commission is concerned about the misuse of passive verification to substitute a different brand and manufacturer of lenses. If a seller knows or should know that a verification request includes a different brand and manufacturer than that prescribed by the prescriber, the verification request is not valid and does not commence the eight-business-hour verification period.”



FEDERAL TRADE COMMISSION
PROTECTING AMERICA'S CONSUMERS

\$3.5 million FTC settlement with Hubble signals that ignoring the Contact Lens Rule can be costly

Excerpts from: <https://www.ftc.gov/business-guidance/blog/2022/01/35-million-ftc-settlement-hubble-signals-ignoring-contact-lens-rule-can-be-costly>

As a result of a [\\$3.5 million FTC settlement](#), Vision Path – the online seller of Hubble contacts – must eye its legal responsibilities through a stronger lens.

Vision Path sells its own Hubble contacts directly to consumers through an online subscription model. The [complaint](#) alleges the defendant violated the Contact Lens Rule by: 1) failing to properly verify consumers' prescriptions; 2) selling contacts after prescription verification requests were denied; 3) altering prescriptions by substituting its own Hubble brand when that wasn't what the consumer was prescribed; and 4) failing to maintain required records.

You'll want to read the [complaint](#) to put the charges in focus, but here are just two allegations that merit a second look. The FTC says in many cases, Hubble either didn't make the required verification calls or made calls that were incomplete or incomprehensible. For example, sometimes the company left voicemails on phone numbers that clearly weren't eye care offices and yet took the prescriber's failure to respond to the call it didn't receive as "passive verification." In other instances, Hubble conveyed its verification messages in a garbled robotic computer voice that was hard to understand. In still other cases, Hubble played those messages over "you're on hold" music when it should have been clear that no one from the prescriber's office was listening.

In addition, the [complaint](#) alleges that the company violated the Contact Lens Rule by substituting Hubble lenses for what consumers' eyecare professional had prescribed. According to the FTC, the defendant did that even when it was apparent that the prescriber hadn't fitted the consumer for Hubble lenses. In some instances, Hubble switched people even after prescribers told the company they didn't prescribe Hubble contacts.

The FTC alleges that consumers were injured by the company's practices. For example, some people received lenses that their medical professional hadn't prescribed for them and for which they hadn't been fitted. According to the complaint:

A Hubble conducted survey, which asked consumers to select the top three reasons for cancelling their subscription, found 24% of customer cancellations were because the customers needed multifocal or toric lenses (which Hubble doesn't make or sell), 13% were because customers said they 'couldn't see out the lenses' (which should not occur if they had been fitted for the lenses), 22% were because customers found the lenses uncomfortable (likewise, in most instances), and 18% were because the customers' eye care prescribers would not let them wear Hubble lenses.

The complaint also charges Hubble with violating the FTC Act by making promises to consumers that it didn't keep. For example, despite repeated assurances that Hubble would "reach out to your doctor on your behalf to ensure we have the right information," the FTC says that Hubble relied instead on faulty verification practices, which often resulted in passive verification and consumers receiving lenses they hadn't been fitted for.



November 10, 2023

The Honorable Cathy McMorris Rodgers
Committee Chair
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chair McMorris Rogers and Ranking Member Pallone,

On behalf of the undersigned, I write to express our strong support for the Contact Lens Prescription Verification Modernization Act, HR 2748. This important piece of legislation promotes patient eye safety by modernizing the way consumers purchase contact lenses while maintaining their right to choose where they purchase their prescribed lenses.

The Federal Trade Commission's (FTC) Contact Lens Rule gives patients the right to receive written prescriptions and purchase lenses from any legitimate seller. It also sets requirements for how doctors release prescriptions to their patients and how sellers verify those prescriptions with doctors. Under the law, providers must release prescriptions to patients, and sellers must verify the contents of the prescription with the provider via phone, fax, or electronic means (emails or web portals).

Unfortunately, the process for sellers verifying the accuracy of patient prescriptions with providers has not kept up with the considerable technological advances, thereby putting patient safety at risk. In recent years, online contact lens sellers have increasingly relied on automated phone messages or "robocalls" to verify the accuracy of patient prescriptions with providers. Robocalls put patient safety in serious jeopardy because they offer no paper trail to verify a prescription, are often inaudible, are often received by non-physicians, and typically do not offer a way for a provider to correct an inaccuracy because the provider is not talking to a live human. If a doctor does not verify the prescription within 8 hours, it is considered "passively verified." Unfortunately, these messages, which come in at all hours of the day and night, make it extremely difficult for a provider to sift through robotic voicemails while simultaneously seeing patients in-clinic.

To ensure access while still putting a premium on patient safety, other federal agencies have incentivized or required modern technology in medical settings, and providers across the country have currently utilized email, patient portals, and electronic medical records. Moreover, a more significant percentage of contact lenses sold in the United States are purchased by patients online. Those online retailers almost universally use automated email messages to confirm an order or



product shipment and for marketing purposes. This clearly demonstrates the retailers' ability to communicate and confirm products through electronic messaging like email.

We believe it is important for the federal government to issue consistent and commonsense messages to providers about integrating appropriate technology into their practices. Using robocalls or other automated telephone calls is outdated, unsafe, and not in the best interests of patient safety. Congress has repeatedly expressed concern over robocalls, which can result in patients receiving a lens other than what is prescribed and risk permanent vision loss (as has occurred in over 1,100 cases related to improper contact lens wear, according to the FDA).

To protect the eye health of all contact lens wearers, Representatives Lisa Blunt Rochester (D-DE) and Michael Burgess (R-TX) introduced the Contact Lens Prescription Verification Act (H.R. 2748). It would eliminate the use of robocalls for contact lens prescription verifications and instead require email, live phone call, or fax confirmation of prescriptions. Vision, health, and safety are paramount to the communities we represent, and we believe this is a commonsense step that will safeguard consumers from harmful practices.

Thank you for your consideration.

Sincerely,

Kevin B. Kimble, Esq.
Executive Director
Southern Christian Leadership
Global Policy Initiative (SCL-GPI)

Dr. Charles Steele, Jr.
CEO and President
Southern Christian Leadership
Conference (SCLC)

Brady J. Buckner
Co-Founder and President
FSIC American Innovation and
Opportunity Fund (AIOF)

Leland Marmon
Director of Relations
Great Plains Tribal Chairman's Association

Gustavo Paredes
Board Member
The Hispanic Institute

Shiala King
Director
Global Natives United

Trecia Warnholz
Director of Technology and Communications
Financial Services Innovation Coalition (FSIC)

Dr. Lucenia W. Dunn
President/CEO
Tuskegee Macon County Community
Foundation, Inc.

Wesley Hodges
Founder & CEO
The Hodges Foundation

Gustavo Paredes
Board Member
The Hispanic Institute



NATIONAL CONSUMERS LEAGUE

1701 K Street, NW, Suite 1200 Washington, DC 20006
Main: (202) 835-3323 Fax: (202) 835-0747 www.nclnet.org

March 18, 2024

The Honorable Cathy McMorris Rodgers
Rayburn House Office Building, Rm. 2188
50 Independence Avenue, SW
Washington, DC 20515-4705

The Honorable Frank Pallone
Rayburn House Office Building, Rm. 2107
50 Independence Avenue, SW
Washington, DC 20515-3006

Dear Chairwoman McMorris Rodgers and Ranking Member Pallone,

I am writing to express my strong support for the Contact Lens Prescription Verification Modernization Act (HR 2748) introduced by Representatives Blunt-Rochester and Burgess. This legislation represents a crucial step forward in modernizing federal regulations governing the contact lens market and ensuring the safety and well-being of millions of American consumers who rely on these essential medical devices for vision correction.

As you are well aware, the landscape of the contact lens market has evolved significantly since its inception nearly 70 years ago. Today, approximately 45 million Americans depend on contact lenses for safe and effective vision correction. However, the current federal regulations have failed to keep pace with these changes, leaving thousands of consumers vulnerable to adverse eye health outcomes each year, including keratitis, corneal scarring, ulcers, infections, and even complete vision loss.

One of the primary concerns stems from the outdated prescription verification process mandated by the Federal Trade Commission's Contact Lens Rule. The reliance on automated robocalls for prescription verification is not only inefficient but also potentially hazardous to patient safety. These robocalls often contain incomplete information, are difficult to decipher, and lack a reliable callback mechanism for correcting errors. Moreover, the prevalence of automated robocalls exacerbates the problem, making it nearly impossible for eye doctors to ensure the accuracy of contact lens prescriptions.

In light of advancements in technology and communication methods, it is imperative that we embrace more efficient and secure means of prescription verification. Electronic communication, such as email, offers a far more reliable and accessible alternative to outdated robocall systems. By requiring contact lens sellers to utilize electronic communication methods, we can enhance patient safety, streamline the verification process, and establish a verifiable paper trail for accountability purposes.

The Contact Lens Prescription Verification Modernization Act represents a commonsense approach to addressing these longstanding issues within the contact lens industry. By leveraging modern technologies and promoting transparency in prescription verification procedures, this legislation prioritizes the health and well-being of American consumers.

In conclusion, I commend your leadership in championing this critical legislation and urge your colleagues in Congress to support its swift passage. Together, we can enact meaningful reforms that safeguard the integrity of the contact lens market and protect the vision health of millions of Americans.

Thank you for your unwavering commitment to advancing public health and safety.

Sincerely,

A handwritten signature in black ink, appearing to read "Sally Greenberg". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Sally Greenberg
Chief Executive Officer
National Consumers League
Washington, DC 20006
Sallyg@nclnet.org