

Safety and compliance of prescription spectacles ordered by the public via the Internet

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KEYWORDS

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Standards;
Compliance

Abstract

BACKGROUND: This study investigated prescription spectacles ordered from online vendors and delivered directly to the public for compliance with the optical tolerance and impact resistance requirements for eyewear dispensed in the United States.

METHODS: Ten individuals ordered 2 pairs of spectacles from each of 10 of the most visited Internet vendors, totaling 200 eyewear orders. Spectacles ordered consisted of ranges of lens and frame materials, lens styles, and refractive corrections reflecting current distributions in the United States. Evaluations included measurement of sphere power, cylinder power and axis, add power (if indicated), horizontal prism imbalance, and impact testing.

RESULTS: We received and evaluated 154 pairs of spectacles, comprising 308 lenses. Several spectacles were provided incorrectly, such as single vision instead of multifocal and lens treatments added or omitted. In 28.6% of spectacles, at least 1 lens failed tolerance standards for at least 1 optical parameter, and in 22.7% of spectacles, at least 1 lens failed impact testing. Overall, 44.8% of spectacles failed at least 1 parameter of optical or impact testing.

CONCLUSION: Nearly half of prescription spectacles delivered directly by online vendors did not meet either the optical requirements of the patient's visual needs or the physical requirements for the patient's safety.

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For more than a century, the traditional channel for distribution of prescription spectacles to the public has

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involved trained professionals, such as opticians. Orders could be fulfilled directly, if the practice has finishing capability, or forwarded to a manufacturing laboratory. In either scenario, lenses would be manufactured with parameters to meet impact resistance requirements. The spectacles also would be verified to ensure that their optical properties meet the visual requirements of the prescription and that they are within acceptable tolerances.¹ The patient then would return to the practice to receive the spectacles, where final fit adjustments of the frame could be made.¹ In this manner, the active, personal, i.e., "hands-on,"

dispensing process could protect the patient from spectacles that might not meet applicable requirements. (For the purposes of this report, reference to the word *dispensing* and all its forms will be to its common and commercial meaning as understood within the ophthalmic industry.)

The prevalence of this method through which patients receive prescription spectacles has changed substantially in just the last 4 years. In 2007, a U.S. industry survey found that 5% of the respondents indicated that they purchased spectacles online and that 1.7% of all prescription spectacles were ordered via the Internet and delivered directly to the patient without benefit of a dispensing process.² In 2010, a similar survey estimated that 2.8% of all prescription spectacles were provided directly from online vendors.³ These surveys consistently found that about 28% of consumers consulted Web sites to assist in their most recent purchase of spectacles. By 2014, estimates are that about 4% of all prescription spectacles in the United States will be delivered without the benefit of the traditional dispensing process (personal communication, Steve Kodey, Director of Industry Research, The Vision Council, February 2011). These values represent an average growth rate of > 10% per year.

Because these products are distributed directly to a consumer from Internet vendors, the spectacles arrive without the benefit of the traditional dispensing process, whereby the optical requirements of the prescription⁴ or the impact resistance of the lenses could be confirmed by the ophthalmic dispenser.⁵ This route of direct-to-the-consumer delivery also appears inconsistent (in various degrees) with the requirements of 22 states that regulate those who dispense prescription eyewear but are not doctors, i.e., opticians.⁶ The objective of this study was to investigate compliance with various requirements for prescription spectacles ordered from several popular Internet vendors.

Methods

In early 2010, we identified 12 of the most visited Web sites for ordering prescription spectacles online, based on rankings provided by Alexa[®] Traffic Rank service⁷ (San Francisco, California) and Google PageRank[™] checker⁸ (Mountain View, California). The chosen vendors, thus, would be within the top results of a typical search conducted by the average consumer. All vendors but 1 indicated a physical contact address or toll-free telephone number in the United States or Canada; 1 vendor indicated only an e-mail address for questions and comments.

Ten individuals from around the United States, including the researchers and their colleagues and associates, each placed orders for 2 pairs of spectacle eyewear (see details below) from each of 10 of the target vendors. Seven of the individuals had orders sent to addresses in states that license opticians. Orders were placed over a 2-month period in mid-2010. Thus, a group of orders going to any one vendor would arrive on separate dates. Frame styles were chosen from the low- and midrange options offered by

each vendor, avoiding name brand and designer products. Orders were purchased in the same manner and at the same retail cost as for the typical consumer, including payment of any taxes and shipping and handling charges assessed by the vendor.

Orders were shipped by the vendors via the U.S. Postal Service directly to each individual but were not opened. All eyewear were forwarded to one researcher (DLT), who identified, cataloged, and verified each order. This researcher also conducted optical analyses on the spectacles, described below, as well as verification of the presence of lens treatments, i.e., scratch-resistant (SR) coating, antireflective (AR) coating, and photochromic properties. The spectacles were then forwarded to an independent accredited laboratory for impact resistance testing, utilizing the "drop ball" methodology for measuring impact resistance of dress spectacle lenses.⁵

Spectacle parameters were chosen based on estimated U.S. distribution trends over the previous 2 years, determined by an unpublished internal analysis of dispensed eyewear conducted in early 2010 by Walman Optical Company: refractive power distribution was based on an analysis of more than 27,000 lenses; lens material, coating, and frame type and material distributions were based on an analysis of more than 1 million pairs of eyewear. The distributions for these various parameters are similar to those reported by Edlow and Markus,⁹ with the exception that we did not include orders for glass, trifocal, or polarized lenses. Parameters of child and adult spectacles ordered and evaluated, as well as costs of received eyewear, are shown in Table 1.

All lenses ordered were organic plastic, either hard resin, polycarbonate, or other proprietary materials. Actual lens material choices were based on availability or vendor recommendations, as applicable; in some cases, no choices were provided by the vendor. Table 2 shows the distribution of lens materials ordered and received based on either what was ordered or determined on receipt. The substrate materials for spectacles not included in the tally could not be determined conclusively, and no additional testing was conducted to make such determinations.

Table 3 shows the distribution of refractive corrections ordered and received, as well as measured center thickness (CT) (see below). Ordered sphere powers ranged from -4.00 to +2.25 diopters (D), cylinder powers ranged from -0.25 to -2.25 D, cylinder axes ranged from 30° to 150°, and add powers ranged from +1.50 to +2.25 D. Children's spectacles were ordered with only single-vision myopic or myopic astigmatism corrections. Parameters of received spectacles were within the same nominal ranges. No specialty lenses or styles, such as prism, prescription sun eyewear, occupational progressive lenses, or safety eyewear, were ordered.

Lens analyses included measurement of sphere power, cylinder power and axis, add power (if specified), separation of distance optical centers, and CT. Optical analyses were conducted with a Tomey AutoLensmeter TL-2000B

Table 1 Parameters of spectacles ordered and evaluated

Style	Lens	Coating	Tint	Frame	Intended orders		Received & evaluated		
					Number	Number*	Median (95th percentile)	Range	
Child	Single vision	SR	Clear	Metal	20	11			
				Metal	0	3			
Adult	Single vision	SR	Clear	Metal	1	5			
				Plastic	40	23	\$46.85 (\$213.74)	\$7.95 to \$278.90	
				Metal	0	5			
				Plastic	10	16			
				Photochromic	Plastic	20	15		
	Bifocal	SR	Clear	Metal	20	14			
				Plastic	0	1			
				Photochromic	Metal	10	4	\$78.50 (\$249.90)	\$26.95 to \$259.00
				Metal	0	1			
				AR	Clear	Metal	0	1	
				Plastic	10	6			
Progressive addition	SR	Clear	Metal	49	30				
			Metal	10	15	\$90.75 (\$253.87)	\$38.90 to \$417.00		
			Metal	10	5				
			Photochromic	Metal	10	5			
Total					200	154			

Note: Cost does not include applicable taxes or shipping and handling charges.

* Number of spectacles received with any given set of parameters can be greater than number ordered because of errors in ordering or processing.

(Phoenix, Arizona) and CT was measured with a Mitutoyo Electronic Gage ID-U1025E (Aurora, Illinois). As specified by the current U.S. standard for prescription dress spectacles, ANSI Z80.1-2010¹⁰: for horizontal lens powers of absolute value of ≤ 2.75 D, horizontal prism imbalance was calculated based on the lens powers in the horizontal meridians and the difference between the specified interpupillary distance and the optical center separation; for horizontal lens powers of absolute value > 2.75 D, specified interpupillary distance was compared with the optical center separation. Total near power was measured at the center of the segment for bifocal lenses and at the bottom of the lens for progressive addition lenses and compared with the distance power to determine add power. The Tomey AutoLensmeter allows for all measurements to be taken at the back surface and uses internal software to calculate the add power based on front vertex powers. All optical analysis

results were compared with tolerances allowed by ANSI Z80.1-2010.

We did not assess vertical prism because the online order entry options did not allow specification of vertical positioning of the optical center for single vision or bifocal lenses or the fitting cross for progressive addition lenses. We also did not assess tolerances of the spectacle frames.

Results

Of the 200 pairs of spectacles ordered, we received 156 (78%). In general, the distributions of parameters for received eyewear are comparable to and still representative of our estimate of U.S. trends. However, the analyses below are based on only 154 pairs of spectacles. One vendor consistently required a doctor's verification and thus fulfilled only a single order for 2 pairs of children's spectacles. This was a different ordering process than that of the other vendors. Both pairs of eyewear from this vendor passed all optical tolerances and impact testing, but it would not be meaningful to draw conclusions about this vendor's products on such a limited sample size. We received a minimum of 8 pairs of spectacles from all other vendors who fulfilled orders.

Other vendors claimed prescription verification as a policy but apparently did not deny any unverified orders on that basis. Several vendors accepted all orders placed but, for reasons unknown, did not fulfill all of them and did not charge for those not fulfilled. We did not follow up on the

Table 2 Number of spectacles ordered and received for which lens material and index could be determined

Lens index	Ordered	Received
1.50 (Hard resin)	93	78
1.56 to 1.58	25	24
1.59 (Polycarbonate)	14	14
1.60 to 1.61	6	6
1.67	1	0
Total	139	122

Table 3 Number of lenses ordered and received with each specified type of refractive correction

Refractive correction	Ordered		Received	
	Number	Number	Center thickness, mm	
			Mean (SD)	Range
Myopic	123	95	1.88 (0.340)	0.96 to 2.89
Myopic astigmatism	123	95		
Hyperopic	77	59	2.29 (0.317)	1.51 to 3.31
Hyperopic astigmatism	29	22		
Mixed astigmatism	48	37		
Total	400	308		

Note: For center thickness analyses, lenses were grouped based on plus power in at least 1 meridian (hyperopic, hyperopic astigmatism, and mixed astigmatism) versus no plus power in any meridian (myopic and myopic astigmatism).

missing orders. However, we received no acknowledgment that any vendor denied an order because it was being sent to an address in a state that licenses opticians, and therefore might require the involvement of a professional in the dispensing process.

Several orders were not fulfilled as expected, as indicated in Table 1. In total, 33 of 154 spectacles (21.4%) were not delivered correctly. Some orders were not placed as intended, possibly because of confusing statements or limited ordering menus on the respective Web sites: 1 pair of bifocal and 4 pairs of progressive addition spectacles were ordered incorrectly with single-vision distance lenses. Other orders apparently were placed correctly but were supplied incorrectly: 3 pairs of ordered bifocal spectacles were received with single-vision lenses with total power for near,

i.e., readers, and 25 pairs of eyewear had lens treatments (AR coating or photochromic) either added or omitted. However, because we received no more than 20 pairs of spectacles from any single vendor, we cannot make any meaningful comparisons between vendors or draw any conclusion about the performance of any individual vendor.

Table 4 shows the errors and numbers of failures for parameters of individual lenses and complete spectacles based on ANSI Z80.1-2010 requirements. Of the 154 pairs of spectacles received, 44 pairs (28.6%) contained at least 1 lens that failed at least 1 parameter of optical analysis testing. For the vendors that provided at least 8 pairs of spectacles in this analysis, at least 1 lens of all those received failed at least 1 component of optical testing. Analysis of the various optical parameters shows the following:

Table 4 Number of lens and spectacle errors and tolerance failures, based on ANSI Z80.1-2010 standards

	Total number	Error		Failures	Failure percentage
		Mean (SD)	Range		
Individual lenses					
Sphere power	308	-0.02 (0.116) D	-1.12 to +1.19 D	8	2.6
Cylinder power					
Ordered with cylinder power	154	+0.005 (0.086) D	-0.67 to +0.26 D	4	2.6
Received with cylinder power	197	-0.02 (0.096) D	-0.67 to +0.26 D	12	6.1
					(3.9% of all lenses received)
Cylinder axis	154	-1.28° (12.18)	-78° to +92°	14	9.1
Add power					
Bifocal	60	+0.04 (0.12) D*	-0.20 to +0.65D*	12	20.0
Progressive addition	102	-0.12 (0.12) D*	-1.25 to +0.12 D*	27	26.5
Impact testing	308			59	19.2
Complete spectacles					
Horizontal prism imbalance	154	-0.15 (0.41) Δ	-2.63 to +0.88 Δ	7	4.5
Separation of distance optical centers		0.94 (3.74) mm	-13 to +13 mm		
Optical analysis	154			44	28.6
Impact testing	154			35	22.7
Optical analysis plus impact testing	154			69	44.8

Note: A negative horizontal prism imbalance indicates base in; positive horizontal prism imbalance indicates base out.

* Error calculations do not include lenses received as single vision; however, these lenses are included in the respective tallies of failures.

- Failure of sphere power tolerance of 2 single-vision lenses (including 1 child lens), 5 bifocal lenses, and 1 progressive addition lens.
- For lenses ordered with cylinder power: failure of cylinder power tolerance of 2 bifocal and 2 progressive addition lenses and failure of cylinder axis tolerance of 6 single-vision (all adult lenses), 2 bifocal, and 6 progressive addition lenses.
- For lenses ordered with sphere power *only*: 43 lenses (comprising 2 child single-vision, 3 adult single-vision, 14 bifocal, and 24 progressive addition lenses) were received with cylinder corrections, of which, 4 bifocal and 4 progressive addition lenses failed tolerance for cylinder power.
- For lenses ordered as bifocal: 3 lenses with add powers too high, 1 lens with add power too low, and 8 lenses with no add power, including 2 received as single-vision distance and 6 received as single-vision readers (all lenses received as single-vision readers passed sphere power tolerance based on the total near lens power).
- For lenses ordered as progressive addition: 2 lenses with no add power (received as single-vision distance) and 25 lenses with add power too low; most of the latter errors arose from frames ordered with vertical dimensions too small for the corridor lengths of the respective progressive adds.
- For horizontal prism imbalance: for low powers, 2 single-vision (including 1 child spectacle), 1 bifocal, and 2 progressive addition spectacles with excessive prism power; for high powers, 1 bifocal and 1 progressive addition spectacles with excessive optical center separation.

Based on a review by Torgersen,¹¹ a CT criterion of 1.9 mm for most plastic materials, other than polycarbonate, should allow most lenses to pass the test for impact resistance. In addition, lenses with certain treatments, such as AR coating, would need to be either made thicker or otherwise adjusted in design to pass impact testing.¹¹ Table 5 shows the results of impact testing, based on lens treatments and the stated criterion for CT. We cannot draw any conclusion based on lens substrate material, because not all received materials are known, and some materials were received in as few as 2 lenses. However, all of the 28 lenses known to be polycarbonate passed impact testing, with CT as low as 1.26 mm. This is not surprising, considering that polycarbonate has long been touted to have adequate impact resistance even with CT of 1 mm.¹² Nonetheless, the polycarbonate lenses are included in their respective tallies in Table 5, because most dispensers are able to measure CT but would have difficulty conclusively determining lens material without damaging the lens in some manner.¹

Only 8 lenses were received with photochromic as the only lens treatment, and none of these lenses failed impact testing; all had CT of 1.99 mm or greater. An early study suggests that photochromic treatment alone does not

Table 5 Number of lenses that passed and failed impact testing, based on center thickness and lens treatment

Lens treatment	Center thickness				Total
	≥ 1.9 mm		< 1.9 mm		
	Pass	Fail	Pass	Fail	
SR only	94	0	65	9	168
Other (total)	73	23	17	27	
Photochromic only	8	0	0	0	8
AR only	49	12	13	18	92
AR & photochromic	16	11	4	9	40
Total (for both SR and Other)	167	23	82	36	308

significantly alter a lens' impact resistance¹³; no similar, more recent studies are known. Although it is likely that the photochromic treatments we received are different than the one investigated by Chou and Fong,¹³ we do not have sufficient data to determine their actual effects on the impact resistance of the lenses in this study; they could have contributed to the failure of any or all of the 20 lenses that also had AR coating. Therefore, for statistical analysis, we compared lenses having only SR coating with lenses having either or both AR coating and photochromic treatment. Thus, complex χ^2 analysis demonstrates that there is an overall significant effect ($\chi^2[4] = 72.52, P < 0.001$) and significant effects based on CT ($\chi^2[1] = 14.67, P < 0.001$) and lens treatment ($\chi^2[1] = 46.76, P < 0.001$).

For lenses with AR coating, either alone or with photochromic treatment, 50 of 132 lenses (37.9%) failed impact testing. If we consider CT as well, 27 of 44 lenses (61.4%) with CT < 1.9 mm failed impact testing, whereas only 23 of 88 lenses (26.1%) with CT ≥ 1.9 mm failed impact testing. By comparison, for lenses with SR coating only, impact testing failures occurred in only 9 of 74 lenses (12.2%) with CT < 1.9 mm and none of the 94 lenses with CT ≥ 1.9 mm.

Further analysis of the results shows the following:

- For children's spectacles received: 6 lenses had AR coating, and none had photochromic treatment. Seven of 28 lenses (25.0%), comprising 4 of 14 pairs of spectacles (28.6%), failed impact testing; these lenses had CTs ranging from 1.55 to 1.82 mm, none were polycarbonate, and 5 lenses had AR coating. For lenses that passed impact testing, 8 lenses were known to be polycarbonate (CT range, 1.26 to 1.79 mm) and 13 lenses were of other materials (CT range, 1.52 to 2.12 mm).
- For adult spectacles received: failure on impact testing of 31 of 162 lenses (19.1%) with no plus power in any meridian (i.e., myopic and myopic astigmatism corrections), with CTs ranging from 0.96 to 2.10 mm. For lenses that passed impact testing, 6 lenses were known to be polycarbonate (CT range, 1.56 to 1.91

mm) and 125 lenses were of other materials (CT range, 1.14 to 2.89 mm).

- For adult spectacles received: failure on impact testing of 21 of 118 lenses (17.8%) with plus power in at least 1 meridian (i.e., hyperopic, hyperopic astigmatism, and mixed astigmatism corrections), with CTs ranging from 1.86 to 2.58 mm. For lenses that passed impact testing, 14 lenses were known to be polycarbonate (CT range, 1.82 to 2.83 mm) and 83 lenses were of other materials (CT range, 1.51 to 3.31 mm).

Overall, 31 of 140 adult spectacles (22.1%) had at least 1 lens that failed impact testing, including 15 of 64 single-vision (23.4%), 6 of 26 bifocal (19.2%), and 10 of 50 progressive addition spectacles (20.0%). There were no differences in results based on whether the lens was edged for mounting in a spectacle frame of either metal or plastic construction.

Spectacle cost was compared with pass/fail performance on optical tolerance and impact testing. Calculation of point-biserial correlation coefficients demonstrates no correlation between cost of any type of eyewear (single vision, bifocal, or progressive addition) and optical or impact test results (all $r^2 < 0.10$, all $P > 0.12$).

Discussion

Many patients likely do not realize that, *and many online vendors in this study did not act as though*, spectacle lenses that provide refractive correction are classified in the United States by the U.S. Food and Drug Administration as Class I Medical Devices.⁴ A valid prescription from a licensed doctor is required, optical tolerances should be maintained,¹⁰ and physical requirements, including impact resistance, must be met.^{5,10} As defined by the U.S. Food and Drug Administration, such devices carry minimal risk to the patient if the optical requirements are not met or are manufactured incorrectly or fitted improperly. Nonetheless, visual or systemic symptoms, such as blur, eyestrain, diplopia, or headache, can develop if the spectacle parameters are inaccurate¹⁴ or proper dispensing procedures are not followed.¹ For this study, we were interested only in online vendors who deliver eyewear directly to patients without the benefit of verification and hands-on fitting by an eye care practitioner or optician. Even the sole vendor that insisted on prescription verification before processing an order nonetheless delivered the spectacles directly to our "patient," with no recommendation to return to the prescribing practitioner or other licensed professional to verify the order or adjust the fit of the frame. Likewise, none of the other vendors included such a recommendation, even for orders that were sent to addresses in states that license ophthalmic dispensers.

None of the target vendors were known to have any direct association with any eye care practitioners physically located in the states to which the spectacles were delivered. We also did not determine if any doctors located in those

states directly used any services of these or other online vendors to personally dispense eyewear to patients. In such cases, online ordering of eyewear can be merely a variant of the traditional dispensing process.

In this study, all participating individuals were knowledgeable about eyewear but some had difficulty placing online orders correctly, such that the spectacles ordered were not what was intended per the study design. In addition, some vendors provided the incorrect type of spectacles, even though the order apparently was placed correctly. These errors are potentially problematic for patients who require multifocal corrections but receive single-vision lenses, and especially troubling when the spectacles are dispensed as single-vision readers with full prescription lens power for near vision. Both errors should seldom occur for spectacles dispensed by the traditional method, or, when identified, could readily and easily be corrected before dispensing.

From a manufacturing perspective, it can be labor- or cost-prohibitive, and in some cases even physically impossible, to create products with 100% accuracy or 100% quality control pass rate. The ophthalmic lens industry includes not only lens and frame manufacturers but also prescribing and dispensing doctors and opticians, who often function in a final quality control capacity before a patient is actually provided with eyewear. For an individual device, such as a lens, frame, or complete eyewear, acceptable deviations from an ideal product or group of products, in form or function, are given by various tolerances, specifically, voluntary industry standards for optical parameters and certain physical attributes (e.g., CT, base curve)¹⁰ and federal guidelines for impact resistance.^{5,15}

An early study shows that approximately 25% of the eyewear manufactured by laboratories for the traditional dispensing model fail tolerance for at least 1 optical parameter,¹⁶ which is comparable to the failure rate of 28.2% found in this study. However, although a subsequent unpublished review conducted in 1999 by the Optical Manufacturing Association and Optical Laboratories Association on behalf of the ANSI Z80.1 subcommittee confirms such a failure rate, it finds that the majority of optical failures in the traditional model are identified during secondary inspections before they leave the laboratory manufacturing site, such that no more than about 2% are returned by the dispensing office after delivery. We do not have any evidence that such secondary inspections did or did not occur for the eyewear we received. We also did not investigate the cost, in time or money, or even the possibility, of returning eyewear in this study, either for correction or credit.

Reduced lens thickness and lens treatments, such as AR coating, have long been known to decrease the impact resistance of ophthalmic lenses when used in unacceptable configurations.^{11,17-20} We confirm that reduced CT and other factors of lens and coating designs and applications can increase the risk of lens impact failure. Unpublished internal test results of over 53,000 lenses by Walman Optical Company, conducted between 1994 and 2010, find that <0.5% failed impact testing. This low estimated failure

rate of traditionally dispensed eyewear in the United States suggests that manufacturing laboratories that are aware of the impact resistance requirement take into account CT and other factors when an order including AR coating, or other treatments, is designed and produced.

It is common practice for eye care practitioners to educate their patients as to the need for an accurate prescription and proper fitting, especially with eyewear incorporating progressive addition lenses, safety lenses, or other specialty parameters, and they can advise their patients who are considering purchasing eyewear online to check the vendor's return policy and costs. Nonetheless, eye care practitioners in the United States are prohibited from placing waivers or disclaimers of the liability on the prescriptions they write,²¹ which includes making recommendations, both for and against, where a patient should have the prescription fulfilled. However, doctors can verify the optical properties of eyewear received from another seller.²¹ Unfortunately, the doctor or optician cannot assess the impact resistance of the finished lenses.

Conclusion

We believe that the dispensing process remains a vital and necessary step in the manufacture and delivery of eyewear to best ensure the health and safety of patients who wear spectacles. Members of the public who engage in the purchase of eyewear without an active, personal dispensing process by a trained professional might not receive a product of equal performance, value, or safety.

The only data that exist today indicating the volume or percentage of prescription eyewear ordered online and received directly by patients is essentially anecdotal. To our knowledge, no industry watch group or governmental agency is tracking such information. This lack of data hampers the eye care professions and appropriate federal and state agencies in their ability to ensure compliance with applicable standards and to minimize the potential risks to the public's eye health and safety. Additional studies are needed to fully validate or refute claims of safety and standards compliance for such eyewear.

The results of this study show that regardless of cost, spectacle eyewear ordered without the benefit of a dispensing process can come with significant risk of error in providing the correct type of lenses needed or ordered, the optical parameters that are within acceptable tolerances, and the physical parameters that provide sufficient protection to the wearer. Thus, cost does not appear to be an indicator that the consumer will receive a product of particular quality or safety. Of the spectacles evaluated, more than 1 of every 5 pairs were delivered incorrectly, with features added or omitted; more than 1 of every 4 pairs had at least 1 lens with at least 1 optical parameter out of tolerance; and more than 1 of every 5 pairs had at least 1 lens that did not pass impact testing. Overall, nearly half of the spectacles received directly from online vendors in this study did not meet either the optical requirements of

the patient's visual needs or the physical requirements for the patient's safety.

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Safety and compliance of prescription spectacles ordered by the public via the Internet

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KEYWORDS

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Prism imbalance;
Impact resistance;
Standards;
Compliance

Abstract

BACKGROUND: This study investigated prescription spectacles ordered from online vendors and delivered directly to the public for compliance with the optical tolerance and impact resistance requirements for eyewear dispensed in the United States.

METHODS: Ten individuals ordered 2 pairs of spectacles from each of 10 of the most visited Internet vendors, totaling 200 eyewear orders. Spectacles ordered consisted of ranges of lens and frame materials, lens styles, and refractive corrections reflecting current distributions in the United States. Evaluations included measurement of sphere power, cylinder power and axis, add power (if indicated), horizontal prism imbalance, and impact testing.

RESULTS: We received and evaluated 154 pairs of spectacles, comprising 308 lenses. Several spectacles were provided incorrectly, such as single vision instead of multifocal and lens treatments added or omitted. In 28.6% of spectacles, at least 1 lens failed tolerance standards for at least 1 optical parameter, and in 22.7% of spectacles, at least 1 lens failed impact testing. Overall, 44.8% of spectacles failed at least 1 parameter of optical or impact testing.

CONCLUSION: Nearly half of prescription spectacles delivered directly by online vendors did not meet either the optical requirements of the patient's visual needs or the physical requirements for the patient's safety.

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For more than a century, the traditional channel for distribution of prescription spectacles to the public has

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involved trained professionals, such as opticians. Orders could be fulfilled directly, if the practice has finishing capability, or forwarded to a manufacturing laboratory. In either scenario, lenses would be manufactured with parameters to meet impact resistance requirements. The spectacles also would be verified to ensure that their optical properties meet the visual requirements of the prescription and that they are within acceptable tolerances.¹ The patient then would return to the practice to receive the spectacles, where final fit adjustments of the frame could be made.¹ In this manner, the active, personal, i.e., "hands-on,"

dispensing process could protect the patient from spectacles that might not meet applicable requirements. (For the purposes of this report, reference to the word *dispensing* and all its forms will be to its common and commercial meaning as understood within the ophthalmic industry.)

The prevalence of this method through which patients receive prescription spectacles has changed substantially in just the last 4 years. In 2007, a U.S. industry survey found that 5% of the respondents indicated that they purchased spectacles online and that 1.7% of all prescription spectacles were ordered via the Internet and delivered directly to the patient without benefit of a dispensing process.² In 2010, a similar survey estimated that 2.8% of all prescription spectacles were provided directly from online vendors.³ These surveys consistently found that about 28% of consumers consulted Web sites to assist in their most recent purchase of spectacles. By 2014, estimates are that about 4% of all prescription spectacles in the United States will be delivered without the benefit of the traditional dispensing process (personal communication, Steve Kodey, Director of Industry Research, The Vision Council, February 2011). These values represent an average growth rate of > 10% per year.

Because these products are distributed directly to a consumer from Internet vendors, the spectacles arrive without the benefit of the traditional dispensing process, whereby the optical requirements of the prescription⁴ or the impact resistance of the lenses could be confirmed by the ophthalmic dispenser.⁵ This route of direct-to-the-consumer delivery also appears inconsistent (in various degrees) with the requirements of 22 states that regulate those who dispense prescription eyewear but are not doctors, i.e., opticians.⁶ The objective of this study was to investigate compliance with various requirements for prescription spectacles ordered from several popular Internet vendors.

Methods

In early 2010, we identified 12 of the most visited Web sites for ordering prescription spectacles online, based on rankings provided by Alexa[®] Traffic Rank service⁷ (San Francisco, California) and Google PageRank[™] checker⁸ (Mountain View, California). The chosen vendors, thus, would be within the top results of a typical search conducted by the average consumer. All vendors but 1 indicated a physical contact address or toll-free telephone number in the United States or Canada; 1 vendor indicated only an e-mail address for questions and comments.

Ten individuals from around the United States, including the researchers and their colleagues and associates, each placed orders for 2 pairs of spectacle eyewear (see details below) from each of 10 of the target vendors. Seven of the individuals had orders sent to addresses in states that license opticians. Orders were placed over a 2-month period in mid-2010. Thus, a group of orders going to any one vendor would arrive on separate dates. Frame styles were chosen from the low- and midrange options offered by

each vendor, avoiding name brand and designer products. Orders were purchased in the same manner and at the same retail cost as for the typical consumer, including payment of any taxes and shipping and handling charges assessed by the vendor.

Orders were shipped by the vendors via the U.S. Postal Service directly to each individual but were not opened. All eyewear were forwarded to one researcher (DLT), who identified, cataloged, and verified each order. This researcher also conducted optical analyses on the spectacles, described below, as well as verification of the presence of lens treatments, i.e., scratch-resistant (SR) coating, antireflective (AR) coating, and photochromic properties. The spectacles were then forwarded to an independent accredited laboratory for impact resistance testing, utilizing the "drop ball" methodology for measuring impact resistance of dress spectacle lenses.⁵

Spectacle parameters were chosen based on estimated U.S. distribution trends over the previous 2 years, determined by an unpublished internal analysis of dispensed eyewear conducted in early 2010 by Walman Optical Company: refractive power distribution was based on an analysis of more than 27,000 lenses; lens material, coating, and frame type and material distributions were based on an analysis of more than 1 million pairs of eyewear. The distributions for these various parameters are similar to those reported by Edlow and Markus,⁹ with the exception that we did not include orders for glass, trifocal, or polarized lenses. Parameters of child and adult spectacles ordered and evaluated, as well as costs of received eyewear, are shown in Table 1.

All lenses ordered were organic plastic, either hard resin, polycarbonate, or other proprietary materials. Actual lens material choices were based on availability or vendor recommendations, as applicable; in some cases, no choices were provided by the vendor. Table 2 shows the distribution of lens materials ordered and received based on either what was ordered or determined on receipt. The substrate materials for spectacles not included in the tally could not be determined conclusively, and no additional testing was conducted to make such determinations.

Table 3 shows the distribution of refractive corrections ordered and received, as well as measured center thickness (CT) (see below). Ordered sphere powers ranged from -4.00 to +2.25 diopters (D), cylinder powers ranged from -0.25 to -2.25 D, cylinder axes ranged from 30° to 150°, and add powers ranged from +1.50 to +2.25 D. Children's spectacles were ordered with only single-vision myopic or myopic astigmatism corrections. Parameters of received spectacles were within the same nominal ranges. No specialty lenses or styles, such as prism, prescription sun eyewear, occupational progressive lenses, or safety eyewear, were ordered.

Lens analyses included measurement of sphere power, cylinder power and axis, add power (if specified), separation of distance optical centers, and CT. Optical analyses were conducted with a Tomey AutoLenseMeter TL-2000B

Table 1 Parameters of spectacles ordered and evaluated

Style	Lens	Coating	Tint	Frame	Intended orders		Received & evaluated	
					Number	Number*	Median (95th percentile)	Range
Child	Single vision	SR	Clear	Metal	20	11		
		AR	Clear	Metal	0	3		
Adult	Single vision	SR	Clear	Metal	1	5		
				Plastic	40	23	\$46.85 (\$213.74)	\$7.95 to \$278.90
		AR	Clear	Metal	0	5		
				Plastic	10	16		
	Photochromic	Plastic			20	15		
	Bifocal	SR	Clear	Metal	20	14		
				Plastic	0	1		
		AR	Clear	Photochromic Metal	10	4	\$78.50 (\$249.90)	\$26.95 to \$259.00
				Metal	0	1		
Plastic				10	6			
Progressive addition	SR	Clear	Metal	49	30			
			Metal	10	15			
	AR	Clear	Metal	10	5	\$90.75 (\$253.87)	\$38.90 to \$417.00	
Total					200	154		

Note: Cost does not include applicable taxes or shipping and handling charges.

* Number of spectacles received with any given set of parameters can be greater than number ordered because of errors in ordering or processing.

(Phoenix, Arizona) and CT was measured with a Mitutoyo Electronic Gage ID-U1025E (Aurora, Illinois). As specified by the current U.S. standard for prescription dress spectacles, ANSI Z80.1-2010¹⁰: for horizontal lens powers of absolute value of ≤ 2.75 D, horizontal prism imbalance was calculated based on the lens powers in the horizontal meridians and the difference between the specified interpupillary distance and the optical center separation; for horizontal lens powers of absolute value > 2.75 D, specified interpupillary distance was compared with the optical center separation. Total near power was measured at the center of the segment for bifocal lenses and at the bottom of the lens for progressive addition lenses and compared with the distance power to determine add power. The Tomey AutoLensmeter allows for all measurements to be taken at the back surface and uses internal software to calculate the add power based on front vertex powers. All optical analysis

results were compared with tolerances allowed by ANSI Z80.1-2010.

We did not assess vertical prism because the online order entry options did not allow specification of vertical positioning of the optical center for single vision or bifocal lenses or the fitting cross for progressive addition lenses. We also did not assess tolerances of the spectacle frames.

Results

Of the 200 pairs of spectacles ordered, we received 156 (78%). In general, the distributions of parameters for received eyewear are comparable to and still representative of our estimate of U.S. trends. However, the analyses below are based on only 154 pairs of spectacles. One vendor consistently required a doctor’s verification and thus fulfilled only a single order for 2 pairs of children’s spectacles. This was a different ordering process than that of the other vendors. Both pairs of eyewear from this vendor passed all optical tolerances and impact testing, but it would not be meaningful to draw conclusions about this vendor’s products on such a limited sample size. We received a minimum of 8 pairs of spectacles from all other vendors who fulfilled orders.

Other vendors claimed prescription verification as a policy but apparently did not deny any unverified orders on that basis. Several vendors accepted all orders placed but, for reasons unknown, did not fulfill all of them and did not charge for those not fulfilled. We did not follow up on the

Table 2 Number of spectacles ordered and received for which lens material and index could be determined

Lens index	Ordered	Received
1.50 (Hard resin)	93	78
1.56 to 1.58	25	24
1.59 (Polycarbonate)	14	14
1.60 to 1.61	6	6
1.67	1	0
Total	139	122

Table 3 Number of lenses ordered and received with each specified type of refractive correction

Refractive correction	Ordered		Received	
	Number	Number	Center thickness, mm	
			Mean (SD)	Range
Myopic	123	95	1.88 (0.340)	0.96 to 2.89
Myopic astigmatism	123	95		
Hyperopic	77	59	2.29 (0.317)	1.51 to 3.31
Hyperopic astigmatism	29	22		
Mixed astigmatism	48	37		
Total	400	308		

Note: For center thickness analyses, lenses were grouped based on plus power in at least 1 meridian (hyperopic, hyperopic astigmatism, and mixed astigmatism) versus no plus power in any meridian (myopic and myopic astigmatism).

missing orders. However, we received no acknowledgment that any vendor denied an order because it was being sent to an address in a state that licenses opticians, and therefore might require the involvement of a professional in the dispensing process.

Several orders were not fulfilled as expected, as indicated in Table 1. In total, 33 of 154 spectacles (21.4%) were not delivered correctly. Some orders were not placed as intended, possibly because of confusing statements or limited ordering menus on the respective Web sites: 1 pair of bifocal and 4 pairs of progressive addition spectacles were ordered incorrectly with single-vision distance lenses. Other orders apparently were placed correctly but were supplied incorrectly: 3 pairs of ordered bifocal spectacles were received with single-vision lenses with total power for near,

i.e., readers, and 25 pairs of eyewear had lens treatments (AR coating or photochromic) either added or omitted. However, because we received no more than 20 pairs of spectacles from any single vendor, we cannot make any meaningful comparisons between vendors or draw any conclusion about the performance of any individual vendor.

Table 4 shows the errors and numbers of failures for parameters of individual lenses and complete spectacles based on ANSI Z80.1-2010 requirements. Of the 154 pairs of spectacles received, 44 pairs (28.6%) contained at least 1 lens that failed at least 1 parameter of optical analysis testing. For the vendors that provided at least 8 pairs of spectacles in this analysis, at least 1 lens of all those received failed at least 1 component of optical testing. Analysis of the various optical parameters shows the following:

Table 4 Number of lens and spectacle errors and tolerance failures, based on ANSI Z80.1-2010 standards

	Total number	Error		Failures	Failure percentage
		Mean (SD)	Range		
Individual lenses					
Sphere power	308	-0.02 (0.116) D	-1.12 to +1.19 D	8	2.6
Cylinder power					
Ordered with cylinder power	154	+0.005 (0.086) D	-0.67 to +0.26 D	4	2.6
Received with cylinder power	197	-0.02 (0.096) D	-0.67 to +0.26 D	12	6.1
					(3.9% of all lenses received)
Cylinder axis	154	-1.28° (12.18)	-78° to +92°	14	9.1
Add power					
Bifocal	60	+0.04 (0.12) D*	-0.20 to +0.65D*	12	20.0
Progressive addition	102	-0.12 (0.12) D*	-1.25 to +0.12 D*	27	26.5
Impact testing	308			59	19.2
Complete spectacles					
Horizontal prism imbalance	154	-0.15 (0.41) Δ	-2.63 to +0.88 Δ	7	4.5
Separation of distance optical centers		0.94 (3.74) mm	-13 to +13 mm		
Optical analysis	154			44	28.6
Impact testing	154			35	22.7
Optical analysis plus impact testing	154			69	44.8

Note: A negative horizontal prism imbalance indicates base in; positive horizontal prism imbalance indicates base out.

* Error calculations do not include lenses received as single vision; however, these lenses are included in the respective tallies of failures.

- Failure of sphere power tolerance of 2 single-vision lenses (including 1 child lens), 5 bifocal lenses, and 1 progressive addition lens.
- For lenses ordered with cylinder power: failure of cylinder power tolerance of 2 bifocal and 2 progressive addition lenses and failure of cylinder axis tolerance of 6 single-vision (all adult lenses), 2 bifocal, and 6 progressive addition lenses.
- For lenses ordered with sphere power *only*: 43 lenses (comprising 2 child single-vision, 3 adult single-vision, 14 bifocal, and 24 progressive addition lenses) were received with cylinder corrections, of which, 4 bifocal and 4 progressive addition lenses failed tolerance for cylinder power.
- For lenses ordered as bifocal: 3 lenses with add powers too high, 1 lens with add power too low, and 8 lenses with no add power, including 2 received as single-vision distance and 6 received as single-vision readers (all lenses received as single-vision readers passed sphere power tolerance based on the total near lens power).
- For lenses ordered as progressive addition: 2 lenses with no add power (received as single-vision distance) and 25 lenses with add power too low; most of the latter errors arose from frames ordered with vertical dimensions too small for the corridor lengths of the respective progressive adds.
- For horizontal prism imbalance: for low powers, 2 single-vision (including 1 child spectacle), 1 bifocal, and 2 progressive addition spectacles with excessive prism power; for high powers, 1 bifocal and 1 progressive addition spectacles with excessive optical center separation.

Based on a review by Torgersen,¹¹ a CT criterion of 1.9 mm for most plastic materials, other than polycarbonate, should allow most lenses to pass the test for impact resistance. In addition, lenses with certain treatments, such as AR coating, would need to be either made thicker or otherwise adjusted in design to pass impact testing.¹¹ Table 5 shows the results of impact testing, based on lens treatments and the stated criterion for CT. We cannot draw any conclusion based on lens substrate material, because not all received materials are known, and some materials were received in as few as 2 lenses. However, all of the 28 lenses known to be polycarbonate passed impact testing, with CT as low as 1.26 mm. This is not surprising, considering that polycarbonate has long been touted to have adequate impact resistance even with CT of 1 mm.¹² Nonetheless, the polycarbonate lenses are included in their respective tallies in Table 5, because most dispensers are able to measure CT but would have difficulty conclusively determining lens material without damaging the lens in some manner.¹

Only 8 lenses were received with photochromic as the only lens treatment, and none of these lenses failed impact testing; all had CT of 1.99 mm or greater. An early study suggests that photochromic treatment alone does not

Table 5 Number of lenses that passed and failed impact testing, based on center thickness and lens treatment

Lens treatment	Center thickness				Total
	≥ 1.9 mm		< 1.9 mm		
	Pass	Fail	Pass	Fail	
SR only	94	0	65	9	168
Other (total)	73	23	17	27	
Photochromic only	8	0	0	0	8
AR only	49	12	13	18	92
AR & photochromic	16	11	4	9	40
Total (for both SR and Other)	167	23	82	36	308

significantly alter a lens' impact resistance¹³; no similar, more recent studies are known. Although it is likely that the photochromic treatments we received are different than the one investigated by Chou and Fong,¹³ we do not have sufficient data to determine their actual effects on the impact resistance of the lenses in this study; they could have contributed to the failure of any or all of the 20 lenses that also had AR coating. Therefore, for statistical analysis, we compared lenses having only SR coating with lenses having either or both AR coating and photochromic treatment. Thus, complex χ^2 analysis demonstrates that there is an overall significant effect ($\chi^2[4] = 72.52, P < 0.001$) and significant effects based on CT ($\chi^2[1] = 14.67, P < 0.001$) and lens treatment ($\chi^2[1] = 46.76, P < 0.001$).

For lenses with AR coating, either alone or with photochromic treatment, 50 of 132 lenses (37.9%) failed impact testing. If we consider CT as well, 27 of 44 lenses (61.4%) with CT < 1.9 mm failed impact testing, whereas only 23 of 88 lenses (26.1%) with CT ≥ 1.9 mm failed impact testing. By comparison, for lenses with SR coating only, impact testing failures occurred in only 9 of 74 lenses (12.2%) with CT < 1.9 mm and none of the 94 lenses with CT ≥ 1.9 mm.

Further analysis of the results shows the following:

- For children's spectacles received: 6 lenses had AR coating, and none had photochromic treatment. Seven of 28 lenses (25.0%), comprising 4 of 14 pairs of spectacles (28.6%), failed impact testing; these lenses had CTs ranging from 1.55 to 1.82 mm, none were polycarbonate, and 5 lenses had AR coating. For lenses that passed impact testing, 8 lenses were known to be polycarbonate (CT range, 1.26 to 1.79 mm) and 13 lenses were of other materials (CT range, 1.52 to 2.12 mm).
- For adult spectacles received: failure on impact testing of 31 of 162 lenses (19.1%) with no plus power in any meridian (i.e., myopic and myopic astigmatism corrections), with CTs ranging from 0.96 to 2.10 mm. For lenses that passed impact testing, 6 lenses were known to be polycarbonate (CT range, 1.56 to 1.91

mm) and 125 lenses were of other materials (CT range, 1.14 to 2.89 mm).

- For adult spectacles received: failure on impact testing of 21 of 118 lenses (17.8%) with plus power in at least 1 meridian (i.e., hyperopic, hyperopic astigmatism, and mixed astigmatism corrections), with CTs ranging from 1.86 to 2.58 mm. For lenses that passed impact testing, 14 lenses were known to be polycarbonate (CT range, 1.82 to 2.83 mm) and 83 lenses were of other materials (CT range, 1.51 to 3.31 mm).

Overall, 31 of 140 adult spectacles (22.1%) had at least 1 lens that failed impact testing, including 15 of 64 single-vision (23.4%), 6 of 26 bifocal (19.2%), and 10 of 50 progressive addition spectacles (20.0%). There were no differences in results based on whether the lens was edged for mounting in a spectacle frame of either metal or plastic construction.

Spectacle cost was compared with pass/fail performance on optical tolerance and impact testing. Calculation of point-biserial correlation coefficients demonstrates no correlation between cost of any type of eyewear (single vision, bifocal, or progressive addition) and optical or impact test results (all $r^2 < 0.10$, all $P > 0.12$).

Discussion

Many patients likely do not realize that, *and many online vendors in this study did not act as though*, spectacle lenses that provide refractive correction are classified in the United States by the U.S. Food and Drug Administration as Class I Medical Devices.⁴ A valid prescription from a licensed doctor is required, optical tolerances should be maintained,¹⁰ and physical requirements, including impact resistance, must be met.^{5,10} As defined by the U.S. Food and Drug Administration, such devices carry minimal risk to the patient if the optical requirements are not met or are manufactured incorrectly or fitted improperly. Nonetheless, visual or systemic symptoms, such as blur, eyestrain, diplopia, or headache, can develop if the spectacle parameters are inaccurate¹⁴ or proper dispensing procedures are not followed.¹ For this study, we were interested only in online vendors who deliver eyewear directly to patients without the benefit of verification and hands-on fitting by an eye care practitioner or optician. Even the sole vendor that insisted on prescription verification before processing an order nonetheless delivered the spectacles directly to our "patient," with no recommendation to return to the prescribing practitioner or other licensed professional to verify the order or adjust the fit of the frame. Likewise, none of the other vendors included such a recommendation, even for orders that were sent to addresses in states that license ophthalmic dispensers.

None of the target vendors were known to have any direct association with any eye care practitioners physically located in the states to which the spectacles were delivered. We also did not determine if any doctors located in those

states directly used any services of these or other online vendors to personally dispense eyewear to patients. In such cases, online ordering of eyewear can be merely a variant of the traditional dispensing process.

In this study, all participating individuals were knowledgeable about eyewear but some had difficulty placing online orders correctly, such that the spectacles ordered were not what was intended per the study design. In addition, some vendors provided the incorrect type of spectacles, even though the order apparently was placed correctly. These errors are potentially problematic for patients who require multifocal corrections but receive single-vision lenses, and especially troubling when the spectacles are dispensed as single-vision readers with full prescription lens power for near vision. Both errors should seldom occur for spectacles dispensed by the traditional method, or, when identified, could readily and easily be corrected before dispensing.

From a manufacturing perspective, it can be labor- or cost-prohibitive, and in some cases even physically impossible, to create products with 100% accuracy or 100% quality control pass rate. The ophthalmic lens industry includes not only lens and frame manufacturers but also prescribing and dispensing doctors and opticians, who often function in a final quality control capacity before a patient is actually provided with eyewear. For an individual device, such as a lens, frame, or complete eyewear, acceptable deviations from an ideal product or group of products, in form or function, are given by various tolerances, specifically, voluntary industry standards for optical parameters and certain physical attributes (e.g., CT, base curve)¹⁰ and federal guidelines for impact resistance.^{5,15}

An early study shows that approximately 25% of the eyewear manufactured by laboratories for the traditional dispensing model fail tolerance for at least 1 optical parameter,¹⁶ which is comparable to the failure rate of 28.2% found in this study. However, although a subsequent unpublished review conducted in 1999 by the Optical Manufacturing Association and Optical Laboratories Association on behalf of the ANSI Z80.1 subcommittee confirms such a failure rate, it finds that the majority of optical failures in the traditional model are identified during secondary inspections before they leave the laboratory manufacturing site, such that no more than about 2% are returned by the dispensing office after delivery. We do not have any evidence that such secondary inspections did or did not occur for the eyewear we received. We also did not investigate the cost, in time or money, or even the possibility, of returning eyewear in this study, either for correction or credit.

Reduced lens thickness and lens treatments, such as AR coating, have long been known to decrease the impact resistance of ophthalmic lenses when used in unacceptable configurations.^{11,17-20} We confirm that reduced CT and other factors of lens and coating designs and applications can increase the risk of lens impact failure. Unpublished internal test results of over 53,000 lenses by Walman Optical Company, conducted between 1994 and 2010, find that <0.5% failed impact testing. This low estimated failure

rate of traditionally dispensed eyewear in the United States suggests that manufacturing laboratories that are aware of the impact resistance requirement take into account CT and other factors when an order including AR coating, or other treatments, is designed and produced.

It is common practice for eye care practitioners to educate their patients as to the need for an accurate prescription and proper fitting, especially with eyewear incorporating progressive addition lenses, safety lenses, or other specialty parameters, and they can advise their patients who are considering purchasing eyewear online to check the vendor's return policy and costs. Nonetheless, eye care practitioners in the United States are prohibited from placing waivers or disclaimers of the liability on the prescriptions they write,²¹ which includes making recommendations, both for and against, where a patient should have the prescription fulfilled. However, doctors can verify the optical properties of eyewear received from another seller.²¹ Unfortunately, the doctor or optician cannot assess the impact resistance of the finished lenses.

Conclusion

We believe that the dispensing process remains a vital and necessary step in the manufacture and delivery of eyewear to best ensure the health and safety of patients who wear spectacles. Members of the public who engage in the purchase of eyewear without an active, personal dispensing process by a trained professional might not receive a product of equal performance, value, or safety.

The only data that exist today indicating the volume or percentage of prescription eyewear ordered online and received directly by patients is essentially anecdotal. To our knowledge, no industry watch group or governmental agency is tracking such information. This lack of data hampers the eye care professions and appropriate federal and state agencies in their ability to ensure compliance with applicable standards and to minimize the potential risks to the public's eye health and safety. Additional studies are needed to fully validate or refute claims of safety and standards compliance for such eyewear.

The results of this study show that regardless of cost, spectacle eyewear ordered without the benefit of a dispensing process can come with significant risk of error in providing the correct type of lenses needed or ordered, the optical parameters that are within acceptable tolerances, and the physical parameters that provide sufficient protection to the wearer. Thus, cost does not appear to be an indicator that the consumer will receive a product of particular quality or safety. Of the spectacles evaluated, more than 1 of every 5 pairs were delivered incorrectly, with features added or omitted; more than 1 of every 4 pairs had at least 1 lens with at least 1 optical parameter out of tolerance; and more than 1 of every 5 pairs had at least 1 lens that did not pass impact testing. Overall, nearly half of the spectacles received directly from online vendors in this study did not meet either the optical requirements of

the patient's visual needs or the physical requirements for the patient's safety.

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