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To: Board Members **Date:** August 4, 2017

From: Jessica Sieferman
Executive Officer **Telephone:** (916) 575-7170

Subject: **Agenda Item 12 – Update, Discussion and Possible Action on ARBO Annual Meeting Summary; ARBO Survey Request**

Background:

The Association of Regulatory Boards of Optometry (ARBO), made up of 66 regulatory boards throughout the United States, Canada, Australia, and New Zealand, is the forum for all optometry licensing and regulatory agencies to meet, develop, and exchange ideas.

ARBO’s mission “*is to represent and assist member licensing agencies in regulation the practice of optometry for the public welfare.*” ARBO played a key role in the development of optometric laws; the development of a uniform curriculum for optometry schools; and the accreditation of schools and colleges of optometry.

In conjunction with the Association of Schools and Colleges of Optometry (ASCO), ARBO created the National Board of Examiners in Optometry (NBEO). ARBO continues to provide programs to accredit optometric continuing education courses, to track and audit the CE attendance of licensed optometrists and to assist with license mobility. ARBO serves as a conduit for sharing information among licensing boards to help them increase efficiency and decrease costs.

Each year, ARBO holds a meeting for representatives from all regulatory boards to come together and discuss national issues impacting the regulatory boards and the practice of optometry. The Executive Officer attended the three-day meeting in June. A summary of some key topics is below. All meeting materials, including member reports, ARBO’s 2018 budget, and NBEO reports can be found here: <https://guidebook.com/guide/93305/> and entering the passphrase arbo2017dc.

NBEO Workshop

NBEO’s President announced the retirement of NBEO’s Executive Director, Dr. Jack Terry, OD. Dr. Jill Bryant, OD is serving as Interim Executive Director until they find a permanent replacement. NBEO representatives, including their psychometrician, provided an overview of the three-part national examination and their processes to monitor the validity and defensibility of the examination.

NBEO also announced their laser procedure examination currently under development. With more states authorizing optometrists to perform laser procedures, NBEO recognized the need to create a standard competency exam that can be offered to all interested optometrists. The exact completion date is unknown, but updates will be provided to members as available.

ARBO Financial Report

An independent audit was conducted on ARBO's financial statements in accordance with auditing standards generally accepted in the United States. Those standards required the auditor to plan and perform the audit to obtain reasonable assurance about whether the financial statements are free from materials misstatement. The audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements.

In the auditor's opinion, "the financial statements [...] present fairly, in all materials respects, the financial position of Association of Regulatory Boards of Optometry, Inc., as of December 31, 2016 and the changes in its net assets and its cash flows for the year then ended in accordance with accounting principles generally acted in the United States of America."

During a prior Board meeting, Board members expressed interest in viewing financial records related to ARBO and its Council on Optometric Practitioner Education (COPE) program. These financial records can be viewed [here](#) (passphrase: arbo2017dc).

National Board Examination Review Committee (NBERC) Report

The purpose of the NBERC is to review and ensure that the content and process of the NBEO are current and appropriate for ARBO Member Boards. NBERC also evaluates the policies and procedures of the NBEO that might impact the validity and reliability of the examination and reviews how information is presented to both candidates and licensing agencies. NBERC is charged with validating the examination process on behalf of the jurisdictional agencies utilizing the examinations for licensure.

NBERC's written report is attached for reference (Attachment 1).

Legal Update

Dale Atkinson, ARBO's legal counsel, provided an overview of 2016 litigation which may impact regulatory Boards. The presentation is attached for reference (Attachment 2). The presentation included an overview of the Yontz v. Department of Health, Board of Optometry in Florida. This case will be discussed during Agenda Item 19.

Illegal Decorative Contact Lenses: Drama at a Price

Representatives from the US Food and Drug Administration (FDA) provided an overview of the dangers of decorative/cosmetic contact lenses and their work to stop the illegal distribution of these lenses. The FDA reported receiving numerous reports of corneal ulcers/microbial keratitis and blindness associated with some decorative contact lenses. The most common groups affected are adolescents and young adults.

The FDA reported their "disturbing discovers" after their Forensic Chemistry Center in Ohio tested nearly 350 decorative, non-corrective lenses. The results were published in the Journal of Forensic Sciences and can be viewed [here](#).

The abstract indicated that "60% of the counterfeit lenses and 27% of the unapproved lenses examined were positive for microbial contamination. Twenty-nine different brands of noncorrective contact lenses were examined, and 48% of them had at least one sample positive for microbial contamination. Each microorganism was further identified using DNA sequencing. Contaminated contact lenses are associated with numerous health risks, including ocular infections and conjunctivitis leading to permanent visual impairment or blindness. These results support the contention that acquiring contact lenses without a prescription is a considerable threat to consumer health and safety."

In response, the FDA developed an in-depth Communication Strategy, which included a comprehensive contact lens website devoted to contact lenses, partnering with Center of Disease Control, developing a flyer, publishing several consumer-focused articles distributed to over 75,000 subscribers, developing an FDA video targeting youth during Halloween and several public service videos.

They also launched a Twitter Campaign targeting audiences of major meetings/conferences/movie releases featuring the lenses: Twilight Conferences (nationwide), Comic-Con, Hunger Games movie release, Chicago Comic & Entertainment Expo, Anime Boston.

The FDA presented ways regulatory agencies and licensees can help. In July, the Executive Officer met with the DCA's Division of Investigation and California Department of Public Health's Food and Drug Branch (who partners with the FDA) to develop a joint-investigation strategy to protect California consumers. In the following months, staff will work with DCA's Communications Team to develop additional outreach material for the Board. Staff will also seek input from the Public Relations and Outreach Committee.

The entire presentation is attached (Attachment 3).

NBEO Survey

The NBEO has requested the Board's feedback from each regulatory board on some potential changes to the NBEO exams. Please discuss the attached survey (Attachment 4) and determine what responses, to submit to the NBEO.

Attachments

1. NBERC's Written Report
2. Legal Update from Dale Atkinson
3. FDA's Presentation on Illegal Cosmetic Contact Lenses
4. NBEO Survey



NATIONAL BOARD EXAMINATION REVIEW COMMITTEE (NBERC)

NBEO Part I, Part II & Part III Council Meeting
Charlotte, North Carolina: October 21 – 23, 2016

NBERC MEMBERS PRESENT

Thomas Bobst, O.D.—Ohio – Chair
Mary Lou French, O.D.—Illinois
Gary Avallone, O.D.—Louisiana
Clay McLaughlin, O.D.—Oklahoma
Patrick O’Neill, O.D.—ARBO Board Liaison
Ron Cassel, CPB – ARBO Staff

Part I – Applied Basic Science (ABS) Council

Sue Cotter, O.D.
Denise Goodwin, O.D.
Lynn Greenspan, O.D.
Chris Guier, O.D.
Dan Roberts, O.D.
Muriel Schornack, O.D.
Christina Wilmer, O.D.
Board Liaison: Al King, O.D.
NBEO Staff: Rick Present

Part II – Patient Assessment & Management (PAM) Council

Matt Cordes, O.D.
William Denton, O.D.
Joan Miller, O.D.
Dawn Pewitt, O.D.
Trey Sullins, O.D.
Marc Taub, O.D.
Board Liaison: Jill Martinson-Redekopp, O.D.
NBEO Staff: Nicole Stefani, O.D.

Part III – Clinical Skills Council

James Aylward, O.D.
Rex Ballinger, O.D.
Kim Even, O.D.
Brian Kawasaki, O.D.
Chris Lievens, O.D.
Gregory Zink, O.D.
Board Liaison: Jerry Richt, O.D.
NBEO Staff: Lyndon Wong, O.D.

ARBO National Board Examination Review Committee members (NBERC)

Thomas Bobst, O.D. - Chair
Mary Lou French, O.D.
Gary Avallone, O.D.
Clay McLaughlin, O.D.
Patrick O'Neill, O.D. – ARBO Board Liaison
Ron Cassel, CPB - ARBO Staff

Association of Schools and College of Optometry (ASCO)

Karla Zadnik, O.D., MCO, Big Rapids, MI
David Damari, O.D., President, ASCO and Dean, TOSUCO

NBEO STAFF

Jack Terry, O.D., PhD, - CEO

INTRODUCTION

As contained in the contractual agreement between the National Board of Examiners in Optometry (NBEO) and the Association of Regulatory Boards of Optometry (ARBO), the National Board Examination Review Committee (NBERC) shall be an ARBO committee whose purpose is *to review and ensure that the content and process of the National Board Examination is current and appropriate for ARBO Member Boards*. NBERC also evaluates the policies and procedures of the NBEO that might impact the validity and reliability of the examination and reviews how information is presented to both candidates and licensing agencies. NBERC is charged with validating the examination process on behalf of the jurisdictional agencies utilizing the examinations for licensure.

ACKNOWLEDGMENTS

NBERC would like to thank Dr. Jack Terry and the NBEO staff – Rick Present, Nicole Stefani, O.D., Lyndon Wong, O.D. and Andrea Moss for their support of our committee. The NBEO President, William Rafferty, O.D. and CEO, Jack Terry, O.D., PhD were both very generous of their time to respond to requests and questions of the NBERC. NBERC also wants to acknowledge the gracious acceptance and openness of the council members for allowing our observation of the working sessions.

MEETING FORMAT AND COMMITTEE COMPOSITION

The meeting was to review the Part I, Part II, and Part III examinations for the targeted (first time the test is offered after candidates achieve eligibility) and non-targeted (subsequent offering) test days for 2017. The duties of the councils were to determine that the two 2017 examinations measure entry-level ability and evaluate the distribution and balance of the two examinations. Both examinations were compared for equivalence of content and difficulty.

GENERAL COMMENTS

Dr. Terry opened the meeting with introductions of the individuals participating in this the 24th Annual Examinations Councils Meeting process. During the opening session, he reviewed the NBEO website (www.optometry.org) and highlighted included features. He reviewed the

Clinical Skills Examination (CSE) process, including an orientation video, candidate guide, and sample evaluation forms.

Dr. Terry reviewed the testing and scoring processes. Report scores are based on the following: Raw Scores, Percentage Scores and Scaled Scores. These are based on developing a Scale (100-900, 0-99), determining the Cut-Score (Scaling to 300) and maintaining the Scale (Statistical equating).

Dr. Terry reported that the Councils' task is a "big picture" review – Do the items and cases overlap in content and/or cue other items or cases (i.e., is the same content tested in more than one section/session)? Do any particular topics/conditions seem to be over tested/under tested? Are any additional "edits" needed?

Several NBEO objectives were reported as follows:

- One widely accepted standard for licensing tests is that they be absolute rather than norm-referenced.
- Norm-referenced interpretations locate an individual examinee's score relative to the distribution of the scores for some relevant comparison group.
- Criterion-referenced interpretations characterize an examinee without reference to the performance of other individuals.
- One of the most important applications of criterion-referenced tests is to the areas of professional certification and licensure. A typical examination will measure the competencies defining the professional role. Candidate test performance is interpreted in relation to established minimum standards.
- Norm-referenced testing is not defensible for licensure or certification testing as scores are interpreted with respect to being better or worse than others rather than with respect to the level of competence of a specific test taker.

SPECIFIC COMMITTEE OBSERVATIONS

Part I Council – Applied Basic Sciences (ABS) – (made up of 500 test items)

The members of the Committees include:

Part I – Refractive Examination Development Committee

Dr. Sue Cotter – SCCO at MBKU – Fullerton, CA

Dr. Lynn Greenspan – PCO at Salus – Elkins Park, PA

Dr. Muriel Schornack – Mayo Clinic – Rochester, MN

Part I – Disease Examination Development Committee

Dr. Denise Goodwin – Pacific University – Forest Grove, OR

Dr. Christian Guier – Mayo Clinic – Jacksonville, FL

Dr. Dan Roberts – Illinois Eye Institute of ICO – Chicago, IL

Dr. Christina Wilmer – UCBCO

The two Part I Committees (Refraction and Disease) had met previously. New questions are being created, reviewed and make up a significant portion of the total test items. Multiple

response items have been used on testing over the last several years. Dr. Terry presented to NBERC that the cost to make up a new NBEO test question is about \$1600 per question.

We continue to appreciate the Part I council's acceptance of past NBERC recommendations. We encourage the ABS council to continue to maintain the balance in the number of questions in refraction vs. disease. We are pleased to see that a generic vs. brand name drug list and an abbreviation list are now provided to candidates.

Part II Council – Patient Assessment & Management (PAM)

The members of the Committees include:

Part II – Disease Examination Development Committee

Dr. Trey Sullins – Madisonville, TN

Part II – Refractive Examination Development Committee

Dr. Joan Miller – Baseline Vision – Hillsboro, OR

Dr. Marc Taub – Southern College of Optometry - Memphis, TN

The NBEO continues to contract Pearson VUE for the Computer Based Testing (CBT) testing sites. This allows the candidates to take PAM at or closer to their clinical rotation sites instead of having to travel back to their respective school. Some sites have multiple testing centers due to the demand in those particular areas.

The two PAM Committees (Refraction and Disease) had also met previously. The case scenarios continue to undergo extensive modifications. This includes the addition of more multiple response items. The tests also have some longer scenarios with more questions and some less extensive scenarios with fewer questions. This allows testing over broader aspects of the profession. In addition, the council's job was to determine that the examinations (both targeted and non-targeted) measure entry-level ability, evaluate the distribution and balance of the two examinations, and compare both examinations for equivalence of content and difficulty. To achieve this, 20% of the questions are equating questions and are in both examinations.

The PAM examination will consist of 60 simulated patient cases and is administered over two sessions, each 3 ½ hours in length. The distribution of cases by content area is as follows:
Refractive/Sensory Processes/Oculomotor Processes (30%-40% of the cases) and Normal Health/Disease/Trauma (60%-70% of the cases).

Clinical correlations of basic science principles involve about 11%-17%. Diagnosis involves about 20%-34%. Treatment and Management involve about 40%-57%. Legal/Ethics/Public Health issues involve about 4%-10% of the questions.

Each patient case begins with a scenario in which the patient history and clinical data are presented. They usually include at least one visual (e.g. color ophthalmic photographs; contact lens fluorescein pattern; spectacle frame fitting problem; visual field plots; OCT images, etc.). A

24-inch monitor is used for the presentation of images. The scenarios are followed by either 5 or 6 related multiple-choice test items on a separate screen.

Please refer to http://www.optometry.org/pdf/matrix/part_pam_samples.pdf and click on sample test items to see the test format.

Part III Council – Clinical Skills Evaluation (CSE) (1000 test components)

The members of the Committee include:

Part III (CSE)

James Aylward, O.D. – VAOPC – Worcester, MA

Kim Even, O.D. – King of Prussia, PA

The testing center is set up with four testing stations in which 19 clinical skill areas are assessed over a 3.5 hour session involving standardized patients (SP). The National Center for Clinical Testing in Optometry (NCCTO) began operation in August 2012. Part III and the NCCTO continue to be refined and improved.

The NCCTO has 8 exam rooms – two each for each of the four testing stations – allowing for testing of up to 8 candidates in the morning and another 8 in the afternoon for a total of 16 candidates per day. All rooms have multiple cameras recording the candidate performing the required skills. The cameras are so precise that phoropter power and axis can be observed.

The new LASER and Surgical Procedure Room, currently in the evaluation phase, has the following features and procedures: 6 cameras (5 ceiling, 1 in laser) featuring a Duet Lumenis Laser Potential procedures: Chalazion Removal, YAG, SLT and Suturing. Tours are currently available.

Grading is done by onsite OD staff in Station #2. Station #4 has a proctor in the room for standardized patient's (SP) safety. Grading of Stations #1, #3, and #4 are done by a remote evaluator from the extensive video recordings. NCCTO employs 20 part-time onsite evaluators and approximately 80 remote evaluators. Borderline scores are verified by multiple evaluators. Evaluators are regularly compared to their peers to assure consistency.

Intramuscular and intravenous injections are now a required segment of Station 4 of Part III. This skill is performed on a mechanical arm; candidates are evaluated on technique, aseptic procedures, and ability to get desired results. The mechanical arm used in the ISE does not accurately reflect a real-life situation, i.e., the artificial vein falls into a 'channel' and when palpating, one has to look and feel for the concavity rather than a convex vessel.

Twelve states require passing scores on the Injection Skills Examination (ISE). Current ISE passage rates are only around 55%. The Part III Council discussed this area at length, evaluated the grading process, and deemed it appropriate. Are the low passing scores due to student disinterest or a testing procedure that does not adequately reflect a real-life situation?

The CSE is a rapidly evolving testing instrument and appears successful in providing the information necessary for appropriate licensing of new graduates in optometry.

RECOMMENDATIONS AND AREAS OF CONCERN:

1. Given the breadth and scope of modern optometry, it's possible that increasing the size of the NBERC committee would assist in the crucial task. This change would allow for expanded expertise, further division of labor, and enhanced transition and longevity of committee member service. This would allow NBERC to better serve member jurisdictions and the public welfare via in-depth, two-way communication regarding examination content, scoring decisions, psychometrics, etc. and would be consistent with the mission of validating the process.
2. While content experts from academia are highly valued and essential for optimal effectiveness, NBERC has concerns regarding ASCO representatives offering direct input to test design and content. In an era of increased accountability and transparency, such activities could be interpreted as representing unresolved conflicts of interest.
3. As the preparation of an extensive examination is complex, a primer and/or background materials explaining the testing, scoring, and council member selection process/qualifications is recommended. Such materials should also include complete descriptions of the procedures utilized to ensure resolution of conflicts of interest.
4. Given the enormous task, NBERC suggests increasing the size of the various examination councils to assure representation of the depth/breadth of modern scopes of practice. To allow additional feedback to member jurisdictions, NBERC would like to have at least one member attend the meeting of each council to provide more thorough reporting to member boards in order to promote awareness, involvement, and reflection.
5. NBERC has concerns about the intramuscular and intravenous injections that are now a required segment of Station 4 of Part III. This skill is performed on a mechanical arm which does not accurately reflect actual clinical skill sets. ARBO's Member Boards don't see much value in continuing this type of testing. IM skills are almost never used by optometrists and IV skills are rarely used. A particular concern is that the ISE passage rates are only around 55%. NBERC feels that the low passing scores are, in part, because the NBEO is using a testing procedure that does not adequately reflect a real-life situation. There are currently 28 states that permit injections in their scope of practice. It is very likely that many of those are using some other form of certification because they are not confident the ISE is enough to demonstrate they have indeed protected the public.
6. The West Virginia Board of Optometry has a law requiring NBEO to evaluate the subconjunctival injection skill of the candidates. However at this time this skill is not a tested item on the CSE portion of the exam. NBERC feels that although the legal requirement for subconjunctival injection skills testing is unique to West Virginia, the skill should be included in the CSE injection skills test because a number of other states permit subconjunctival injections and that number is increasing. In 2015, the NBEO Clinical Skills Committee indicated they would take steps to implement testing subconjunctival injection skills. We would like to have an update from NBEO on the status of this as we haven't heard back on plans to implement this.
7. To meet the needs of ARBO's member agencies, the NBEO must continually adapt and evolve to implement testing that meets the advancing scope of practice in

optometry. Delays in implementation of testing procedures covering new advances in medical knowledge, supervised training, technology, and practice could represent risk to the public welfare.

8. NBERC developed a survey to ask each state board their thoughts and suggestions regarding the current skills being evaluated in the CSE. The survey was distributed via email on January 9, 2017 and to be returned by February 28, 2017. Twenty (20) states returned the completed survey. Nearly all of the twenty jurisdictions voted to continue testing the current skills. The skill receiving the most votes to replace (4 votes out of 20) was blood pressure measurement. The vote was very evenly split as to including three proposed skills, i.e., Amsler grid (8 Yes, 9 No), all cranial nerve evaluation vs II, III, IV, VI only (8 Yes, 10 No), and Hertel exophthalmometer (9 Yes, 8 No). Only one state (Florida) suggested the addition of testing corneal foreign body removal and lacrimal duct irrigation. All results have been forwarded to the NBEO for consideration.
9. NBERC recommends continuing actions be implemented to prevent further Pearson VUE software update issues from occurring.
10. NBERC endorses the NBEO's development of an enhanced ethics policy and encourages the state regulatory agencies to consider further education in ethical conduct.
11. It is of vital importance that each jurisdiction communicates its individual needs and concerns for testing to ARBO for discussion with NBEO to facilitate proper licensure for the public welfare.

CONCLUSIONS:

The NBERC appreciates the outstanding dedication of the Parts I, II and III council and committee members and the expertise that they lend to the construction of these examinations. We were impressed with the quality of the professionals at the NBEO meeting and their dedication to developing a comprehensive test for candidates. We feel it is a reliable measure of entry-level competence in optometry. We look forward to the continued evolution of the examinations to meet the challenges in assurance of the public welfare.

Respectively submitted,

Thomas Bobst, O.D. - Chair
Mary Lou French, O.D.
Gary Avallone, O.D.
Clay McLaughlin, O.D.
Patrick O'Neill, O.D. – ARBO Board Liaison
Ron Cassel, CPB - ARBO Staff



Association of Regulatory Boards of Optometry, Inc.

Legal Update

Monday, June 19, 2017

8:15 am – 9:30 am

Speaker

Dale J. Atkinson, Esq.
ARBO, General Counsel
Atkinson & Atkinson
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Northbrook, IL 60062
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Agenda

- Big Picture Philosophical Issues
- Cases: Post-North Carolina State Board of Dental Examiners
- Political and Legal Fallout from SCOTUS opinion
- Hutton, et al v. NBEO
- Website accessibility issues – ADA compliance
- FTC proposed revision to 2004 Eyeglass Rule
- Florida Board of Optometry Administrative Rule – NBEO exam within 7 years preceding licensure application
- Other Relevant Regulatory Cases...time permitting....are you kidding?

Big Picture Philosophical Issues....

- Important issues.....
 - **What do optometry boards do?**

Big Picture Philosophical Issues....

- Important issues.....
 - What do optometry boards do?
 - Elevator speeches...
 - “protect the public” ...is not good enough.

Elements of your elevator speech....

- Created by statute
- Standards set forth in law (law includes statutes AND rules/regs)
- Delegated with authority to enforce
- Oversight
- Authorized to promulgate rules/regulations
- Protect the public

- **WRITE YOUR ELEVATOR SPEECH IN 113 WORDS OR LESS**

Elevator speech....

The optometry board is statutorily created and delegated with the authority to regulate the optometry profession in the interest of protecting the health, safety, and welfare of the public. With necessary oversight by government, the board enforces standards and criteria set forth in statute and adds specificity through the promulgation of regulations. The effectiveness and efficiencies of the board is enhanced by populating the board with a combination of consumer members as well as those with the expertise necessary to address the complexities of profession specific issues. An administrative regulatory system provides consumers with an assurance of the qualifications of licensees along with a means of enforcement for the benefit of the public.

Big Picture Philosophical Issues....

- Important issues.....
 - What do optometry boards do?
 - Elevator speeches...

Now back to why “protect the public”..is not good enough.

Institute for Justice v. Department of Financial & Professional Regulation, (Appellate Court Illinois 2017)

- The Illinois Court of Appeals **reversed the lower court and held that the Department of Financial & Professional Regulation (Department) need not produce documents under the Freedom of Information Act (FOIA).** The lower court had granted summary judgment in favor of the **IFJ FOIA request issued to the Department for all complaints regarding licensed cosmetologists and hair braiders.** The lower court also awarded the IFJ \$35K in attorneys fees as a prevailing party. While the original lawsuit was pending, **a new law became effective that provides that complaints under the Barber's Act against licensees are confidential and for use only by the Department and shall not be disclosed except to law enforcement, other regulatory agencies or under a valid subpoena.** The sole issue on appeal was whether the new law was to be applied retroactively, thereby providing an exemption from disclosure. The IFJ argued that retroactive application of the new law impaired its vested right to access to the documents. The court disagreed finding that the exemption from disclosure does not otherwise impair the IFJ right with respect to any completed transaction made in reliance on the prior law, thus has no impermissible retroactive effect. Thus, the disclosure mandate and attorneys fees awards were reversed.

Now what?.....Data

- **Every** board meeting..... **CREATE A RECORD...always think Sunset laws!!**
 - Remind attendees of purpose/mission of board
 - Public meeting...noticed up via statute
 - How meeting will operate/parliamentary procedures
 - No recording devices (controversial if media present)
 - Introduction of board and staff
 - Agenda overview
 - Stats since last meeting
 - Phone calls
 - Website visits
 - Number of applications, issued, denied, average time between completed application and issuance
 - Number of renewal applications, issued, denied, time
 - Complaints, disposition, time, how many pending
 - Other recognitions...education programs, CE providers/programs
 - Disposition of motions from last meeting...accomplishments
 - ...and more.

Post-North Carolina State Board of Dental Examiners

- Numerous lawsuits filed alleging antitrust violations on the part of regulatory boards.....
- Be prepared
 - Knowledge...TRAINING
 - \$\$\$
- Understand the issues
- Seek (and follow) legal advice

Litigation

- **Axcess Medical v. Mississippi State Board of Medical Licensure**
 - Challenge to rules limiting non-licensees from owning clinics; dismissed
- **Coestervms.com, Inc. v. Virginia Real Estate Appraiser Board**
 - Applicant challenged denial of licensure due to past conduct; plaintiff voluntarily dismissed
- **Colindres v. Battle (Georgia Board of Dentistry)**
 - Non-licensee claims antitrust violations, constitutional claims; motion to dismiss pending

Litigation, *cont'd*

- **Henry v. North Carolina Acupuncture Licensing Board**
 - Anticompetitive behavior in excluding physical therapists who perform dry needling
 - Injunction sought; motion to dismiss denied
- **LegalZoom.com, Inc. v. North Carolina State Bar**
 - Challenge to rules restricting legal plans by non-licensee; consent judgment entered

Litigation, *cont'd*

- **Petri v. Virginia Board of Medicine**

- Discipline of licensee for unauthorized practice; Board won at district court; oral argument before Fourth Circuit in March 2016. Affirmed on appeal.

- **Rivera-Nazario v. Corporacion del Fondo del Seguro del Estado**

- Antitrust violations (chiropractors); antitrust claims dismissed, defendants immune and suit dismissed.

- **Robb v. Connecticut Board of Veterinary Medicine**

- Threatened discipline of licensee; licensee claimed antitrust violations; motion to dismiss granted (disciplinary proceeding can move forward).

And yet more litigation....

- **Rodgers v. Louisiana State Board of Nursing**
 - Student challenged termination of university nursing degree program; court held Nursing Board immune under 11th Amendment. Petition to United States Supreme Court denied
- **Rosenberg v. State of Florida**
 - Suspended licensee (lawyer) challenged Grievance Committee and Florida Bar action as anticompetitive; Court dismissed action because FL Bar was a sovereign entity
- **Strategic Pharmaceuticals Solutions, Inc. v. Nevada State Board of Pharmacy**
 - Out of state licensee filed antitrust claims and violation of Nevada Unfair Trade Practices Act; currently pending.

And yet more litigation....

- **Teladoc v. Texas Medical Board**

- Non-licensee challenged rule restricting telemedicine practice and requiring “face to face or in-person evaluation.” Injunction granted and Board motion to dismiss denied. On appeal before 5th Circuit. Appeal abandoned.

- **Wallen v. St. Louis Metropolitan Taxicab Comm’n**

- Uber drivers and customers challenged Commission, members, and cab companies. Injunction sought and motions to dismiss filed; referred to mediation to be done by January 2017.

Political and Legal Fallout Board

- Legislative activity
 - New legislation
- Executive branch activity
 - Executive orders
- Board activity
 - Curtail activities??
- Legal advice to boards and board members re immunity and indemnification

Hutton, et al v. NBEO

2017 U.S. Dist. LEXIS 42008 (U.S.D.C. Maryland, March 22, 2017)

- Two consolidated cases, seeking class action status, as a result of a purported data breach affecting some optometrists.
- Alleged that NBEO suffered a data breach and personal identifiable information (PII) was stolen. Claimed that Amazon Chase credit cards opened in plaintiffs' names as a result of alleged data breach.
- NBEO filed motions to dismiss for lack of subject matter jurisdiction and lack of standing.
- **Court agreed and dismissed complaints— no evidence of data breach, in fact, NBEO denied it suffered a breach. Moreover, threatened injury insufficient – no actual economic injury, increased risk of identity theft or expenses to negate identity theft are not enough to establish injury.**
- Plaintiffs filed notice of appeal to Fourth Circuit on April 19, 2017.

Social Media.....Effects on State Boards

- Fueled interactions between optometrists
- Pros and cons
- Is your board using social media for its messaging?

FTC Revisions to Eyeglass Rule

- <https://www.federalregister.gov/documents/2016/12/07/2016-28471/contact-lens-rule>
- Comments were to be submitted by January 30, 2017
- Proposed rule revision requires prescribers to obtain a signed acknowledgement after releasing a contact lens prescription to the patient
 - <https://www.federalregister.gov/d/2016-28471/p-amd-2>
- **Status??**

Florida Board of Optometry Rule re: Exam

- Rule 64B13-4.001
- Applicants for licensure must obtain passing scores on Parts I – IV of NBE0 within seven (7) year period immediately preceding licensure application
- Rule was challenged and struck down by ALJ as in excess of legislative authority (*Yontz (2017)*)
- **Proposal to revise rule pending?**

Yontz v. Department of Health, Board of Optometry

Case # 16-0666RX State of Florida Division of Administrative Hearings (April 14, 2017)

- Two Applicants licensed in other states, sought licensure in Florida.
- Florida Rule requires applicants for licensure to have passed Parts I thru IV within a 7 year period immediately preceding application.
- Applicants passed exams more than 7 years prior and were denied licensure. Applicants filed lawsuit challenging the Rule.
- Administrative Law Judge found in favor of Applicants and held Rule constituted an invalid exercise of delegated legislative authority.

Ask.....

- Initial application for licensure
- Renewal application
- Application without examination (endorsement)

Website Accessibility...Anticipate Issues

- Section 508 of Rehabilitation Act and Department of Justice guidance re: public accommodations and website accessibility
 - <https://www.section508.gov/>
- WCAG 2.0 – Web Content Accessibility Guidelines
 - <https://www.w3.org/WAI/intro/wcag.php>
 - Department of Justice will likely adopt WCAG 2.0 Level AA as the accessibility standard but final regulations on this not expected until late 2018.
- Each state may also have adopted its own rules re: website accessibility and compliance with disabilities laws.

Other Relevant Regulatory Cases

- Where are the optometry cases?

State Actor...11th Amendment

Ryan v. N.J. State Bd. of Nursing (USDC New Jersey 2017)

- The U.S. District Court in New Jersey **dismissed with prejudice a plaintiff nurse's complaint against the New Jersey State Board of Nursing (Board) and its Executive Director** alleging violations of due process and other state law claims arising out of the Board's suspension of her nursing license. The Board had suspended the license after commencing an investigation due to the nurse's termination from a hospital. The investigation resulted in the Board requiring the nurse to undergo a psychological examination. (The nurse separately sued the evaluating psychologist in a related case: 2016 U.S. Dist. LEXIS 83853, 2016 WL 3533997). The Board moved to dismiss the complaint due to lack of jurisdiction, sovereign immunity, and failure to state a claim. **After analyzing the framework of sovereign immunity and the Eleventh Amendment, the Court held that the Board was an "arm of the state," as any judgment would come from the state treasury, the Board was a "surrogate of the state" and not an "independent agency" because the membership is appointed solely by the governor.** The Court also held that there had been no abrogation of the state's immunity and therefore it lacked jurisdiction to adjudicate plaintiff's claims. The Court also held that the plaintiff's claims for constitutional violations also fail because only the Board and the Executive Director in his official capacity had been named and neither was a "person" amenable to suit under Section 1983. Finally, the Court held the plaintiff's state law claims failed because she failed to provide proper notice under the state Tort Claims Act in a timely manner. All claims were dismissed with prejudice.

Board Bias

Herron v. N.C. Bd. of Examiners for Eng'rs & Surveyors (North Carolina 2017)

- The Court of Appeals of North Carolina reversed the lower court and held that the state Board of Examiners for Engineers and Surveyors (Board) did not violate the Plaintiff's due process rights when it revoked his surveyor's license. **The Plaintiff admitted to having practiced while his license was suspended for failing to complete CE required by the Board. The Board approved the consent agenda at its next meeting** which included a recommendation by its Settlement Conference Committee (Committee) that the Board revoke the license unless the Plaintiff requested a hearing. Notably, none of the Board members reviewed the written materials associated with the Plaintiff's case when it approved the consent agenda. The Plaintiff did in fact request a hearing and the two Board members who served on the Committee recused themselves. **The Plaintiff alleged that, because the Board previously approved the consent agenda, it was prejudiced against him and could not afford a fair hearing.** The Board denied his request that an Administrative Law Judge conduct the hearing and, ultimately, the Board revoked the license. **On judicial appeal, the lower court agreed with the Plaintiff that the Board violated his due process rights and ordered that an ALJ hear the matter de novo. The appellate court reversed, finding that there was no evidence that the Board members were biased at hearing, particularly because none of them actually reviewed the relevant materials before approving the consent agenda.** Additionally, the Board didn't even know at the time that the Committee actually recommended the revocation; it simply approved the consent agenda. The court noted that this process employed by the Board was troublesome, but that such does not imply necessarily bias.

Meeting Minutes..Timeframes

Kean Fed'n of Teachers v. Morell (New Jersey 2017)

- A New Jersey Appellate Court held that a university's board of trustees (Board) violated the state Open Meetings Act (OMA) by not promptly releasing the meeting minutes for two of its meetings but also held that a fixed time frame for such release should not be imposed upon the Board.** A Kean University faculty member was also a member of the Kean Federation of Teachers. Both filed suit against the Board, claiming OMA violations after the Board released minutes of two meetings 94 days and 58 days after the fact, respectively. The lower court held that such releases were not "prompt", as required by law, and imposed a mandate that the Board release meeting minutes within 45 days of each meeting. On appeal, the Board argued that the trial judge failed to consider the circumstances--those being that the Board only meets 4 times per year and must approve a meeting's minutes at the following formal public meeting, thus explaining any delay in release and rendering the 45 day mandate impossible. The appellate court held that, in the interest of public policy, the Board must develop a schedule that allows it to meet more often in order to be prompt in its minutes publication and that the two delays at issue were, in fact, unreasonable. However, it reversed the inflexible 45 day mandate ordered by the lower court, finding that such undermines the Board's autonomy and is managerially and logistically unsound.

Board Certification

Meyer v. McDonald (USDC NY 2017)

- In a civil case, the United States District Court for the Eastern District of New York **granted the defendant\employer's motion for summary judgment thereby dismissing a lawsuit filed by an applicant for employment as a psychiatrist.** Plaintiff alleged age discrimination and retaliation related to previous complaints she filed against the VA. **The court recognized that “board certification” in the medical profession is an appropriate and credible factor to be considered when making hiring decisions.** Thus, the employer was able to defeat plaintiff's attempts to argue that the failure to hire her was a pretext to discrimination.

Policy vs Rule Title Protection

Dunning v. Nev. State Bd. of Physical Therapy Examiners (NV 2016)

- The Nevada Supreme Court reversed the lower court and held that the state Board of Physical Therapy Examiners (Board) engaged in improper rulemaking when it adopted a "policy" related to title protection. The Board adopted a policy prohibiting any physical therapist licensed in Nevada from using the terms "osteopractic" and "osteopractor" in any manner. The continuing education provider who coined the terms filed suit, arguing that the policy was actually a rule and therefore must be subjected to the state's Administrative Procedures Act provisions before being enacted. The district court dismissed the suit in an ambiguous order which the Supreme Court interpreted as being based on lack of subject matter jurisdiction. **The Supreme Court reversed, finding that the courts do have the jurisdiction to consider the case and holding that because the Board's policy is of general applicability to all licensed physical therapists in the state, it is in effect a rule. Therefore, the APA requirements must be followed before it is enacted.** The case was remanded to the lower court.

Time flies...

- Questions and answers (maybe)...
- Many thanks to ARBO and YOU!

Illegal Contact Lenses: Drama at a Price!

Bernard P. Lepri, OD, MS, MEd

**Food & Drug Administration, Center for Devices and
Radiological Health, Office of Device Evaluation**

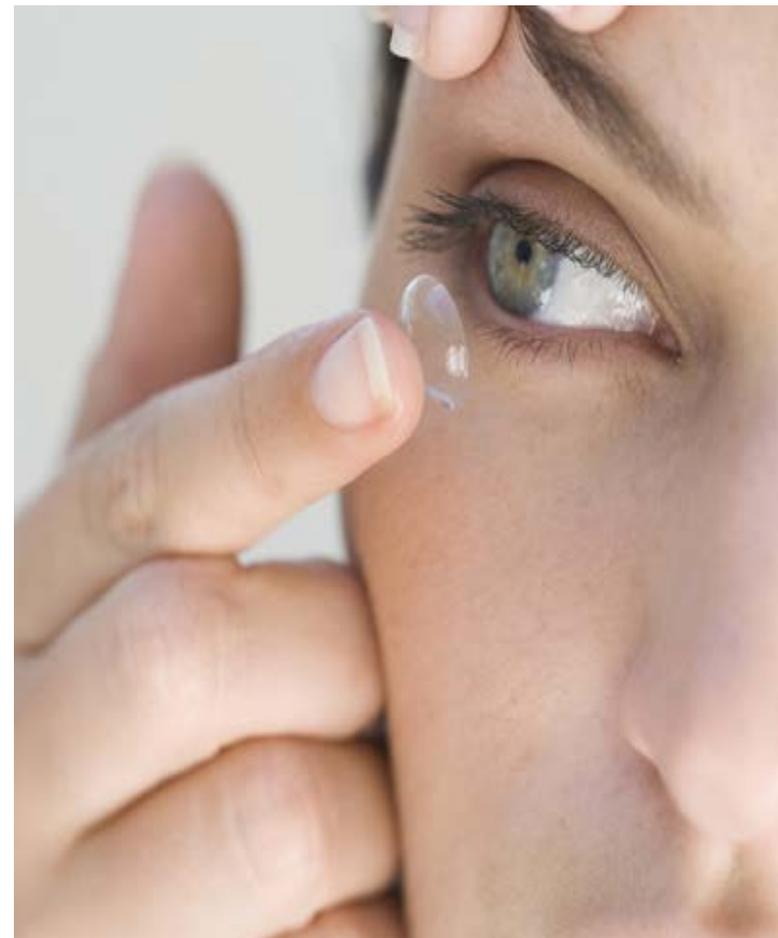
Email: bernard.lepri@fda.hhs.gov

June 19, 2017

Washington, DC

Demographics of Contact Lens Use

- Approximately 41 million Americans wear contact lenses
- 67.7% are female
- 10% under 18 years old
- 15% are between the ages of 18-24 years
- 80% wear soft contact lenses

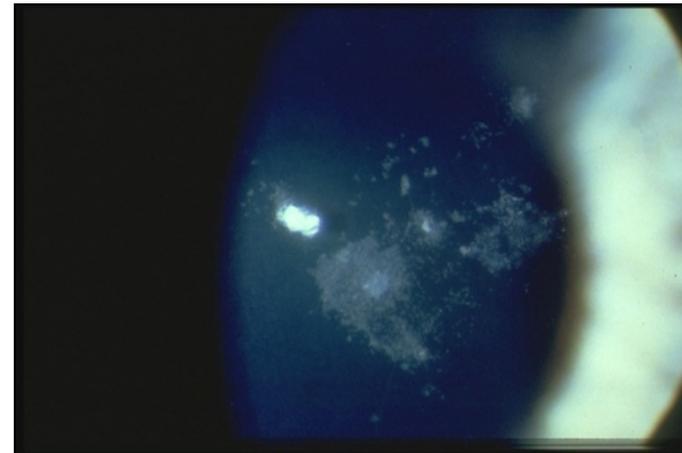
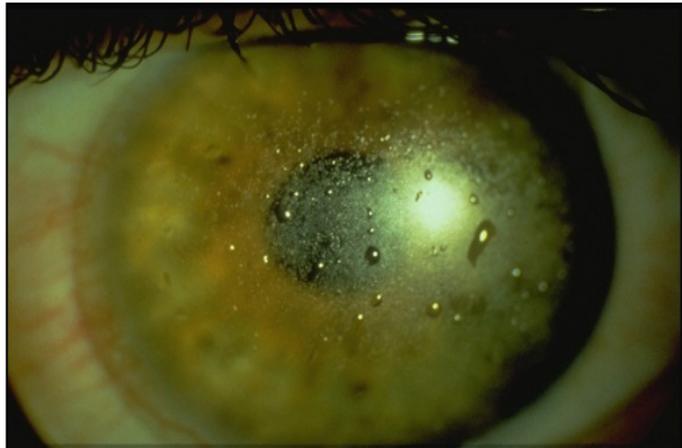


From: JR Cope et al. MMWR 2015;64:865-70.

American Optometric Association. ⁴³Facts and Stats, 2003.



Clinical Evaluation of Contact Lenses



Visual performance

Keratometric performance

Lens movement

Lens deposits

Refractive performance

Lens centration

Lens wettability

Subjective ratings



Care of Contact Lenses

- Cleaning
- Disinfecting
- Hand-washing
- Lens case hygiene
- Wearing time and replacement schedules

Origin of Complications

- 80% of contact lens complications are related to deficient compliance with wear and maintenance care^{*}
- 2% of established contact lens wearers demonstrate good compliance with lens care regimens^{**}

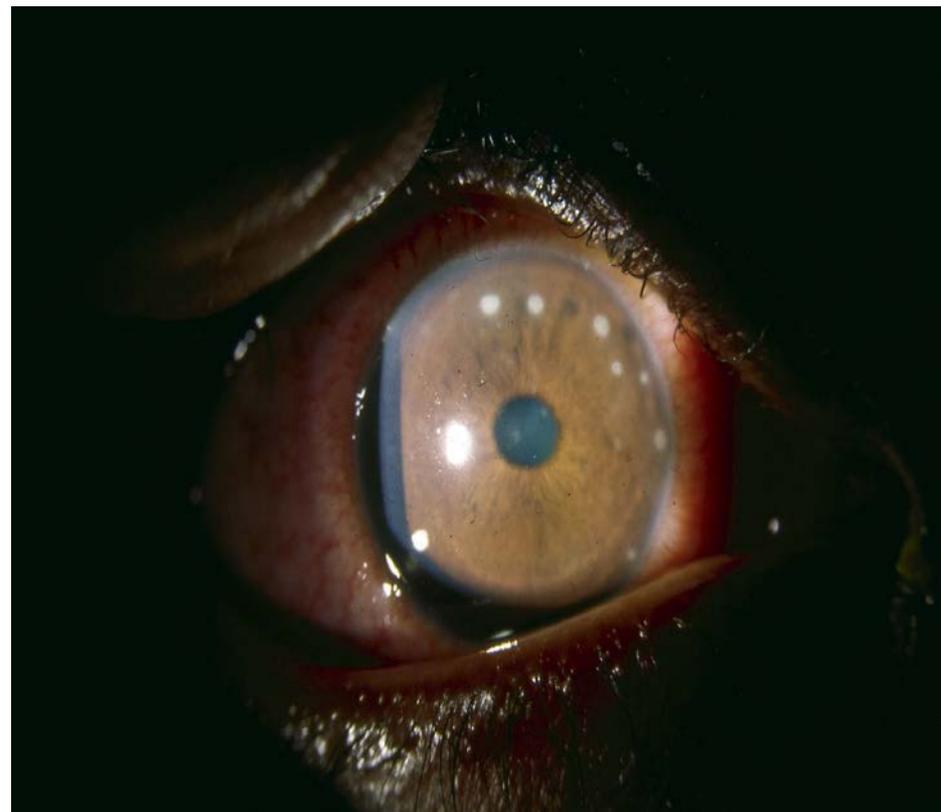
**W Ky et al. CLAO J 1998;24:216-9.*

***DM Robertson et al. Optom Vis Sci 2011;88:1402-8.*

Microbial Keratitis

- Most devastating complication
 - Results in permanent vision loss
- **Signs/Symptoms**
 - Decreased vision, moderate pain, severe eye redness, discharge, tearing, photophobia
- Decorative contact lenses wearers have a 5-fold higher odds of developing microbial keratitis compared to other lens wearers

(T. Bourcier, Abstract 4690, ARVO; 2012)



Regulation of Contact Lenses

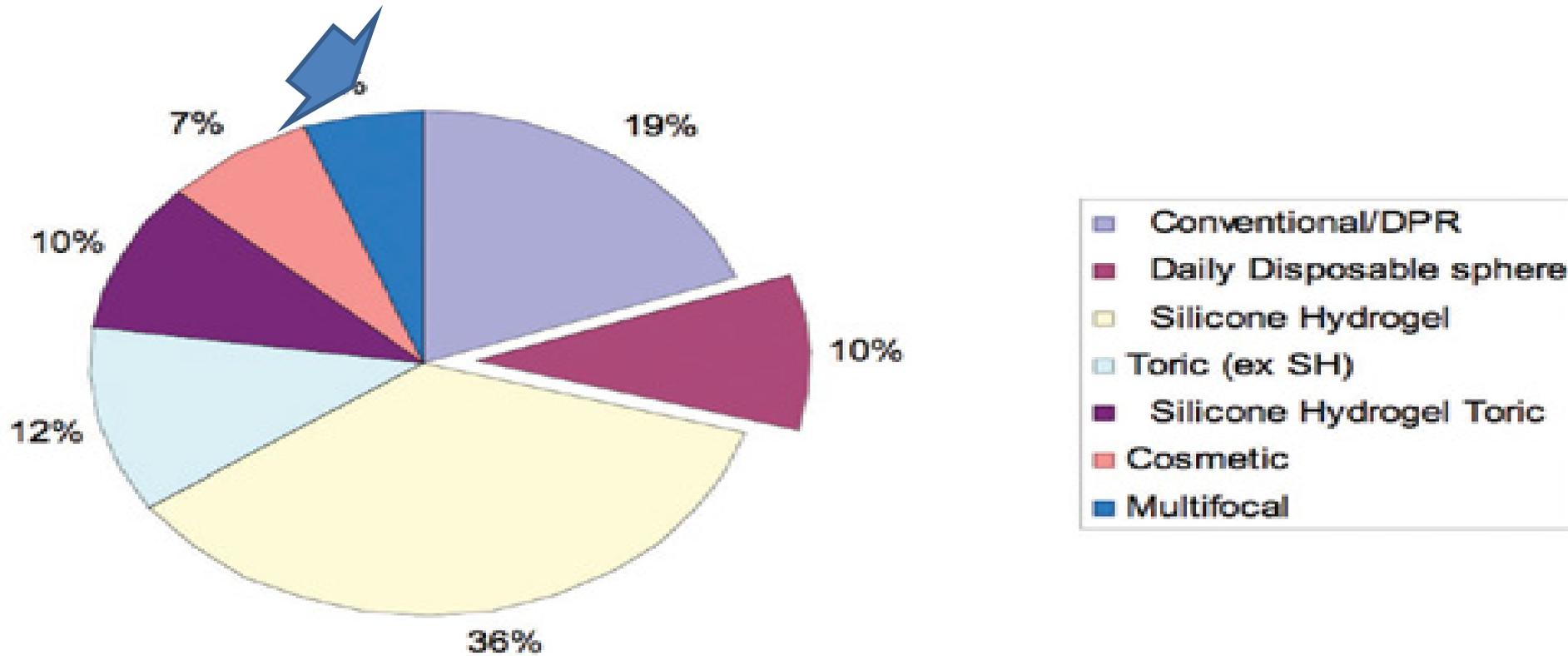
- In 2005, the Food, Drug and Cosmetic Act was amended to classify all contact lenses – including decorative ones – as medical devices
- Typically, Class II 510(k)
 - Premarket notification clearance required for marketing
 - Substantially equivalent to another legally marketed device
 - General and Special Controls
 - Daily Wear Lenses (most decorative lenses)



US Market Trends for Soft Contact Lenses-2007

U.S. Market Share (by Product)

Decorative Lenses





Types of Colored Contacts

- **Visibility tint**
 - No change to eye color, helps with insertion/removal of lens
- **Enhancement tint**
 - Enhance normal eye color (best for light-colored eyes)
- **Opaque tint**
 - **Change eye color**
 - **Costume or theatrical**



Adolescent Uses of Decorative Lenses



Michael Jackson in Thriller Video

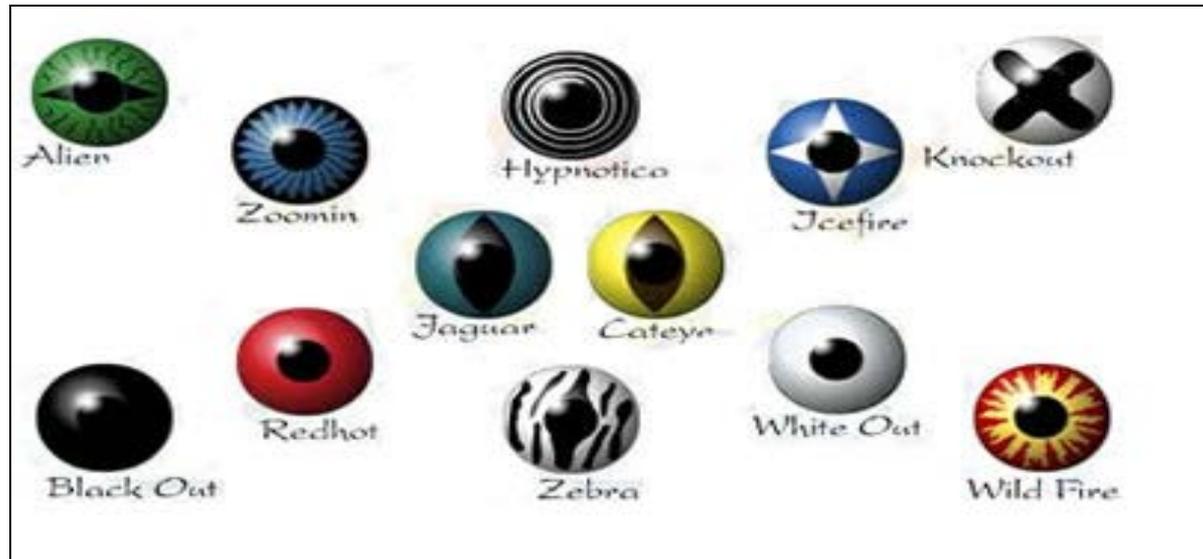


Lady Gaga in Bad Romance Video

Celebrities Popularize these Lenses

Rihanna on the cover of GQ

Decorative/Cosmetic Contact Lenses



- Food and Drug Administration does not recognize over-the-counter sale of contact lenses as legitimate or safe
- Federal Trade Commission took action against 3 Internet Marketers of “Circle” contact lenses in 2011
 - Companies continue to be in violation

Not My Patients!

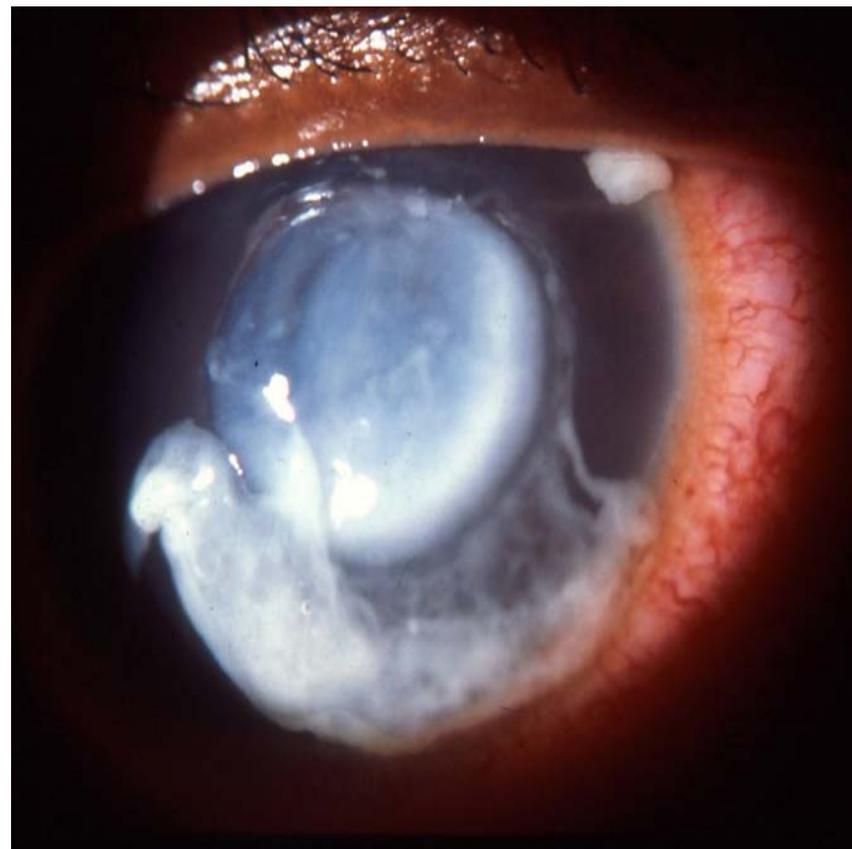
- Survey of metro adolescent clinic population (n=159) aged 12-20 (mean 15.7 years)
 - 45% White, 39% African American, 11% Hispanic and 2% Asian
 - 23% wear decorative lenses and 74% report their friends wear DCL
 - 51% did not have them prescribed by eye care provider

Reported Case from Cleveland

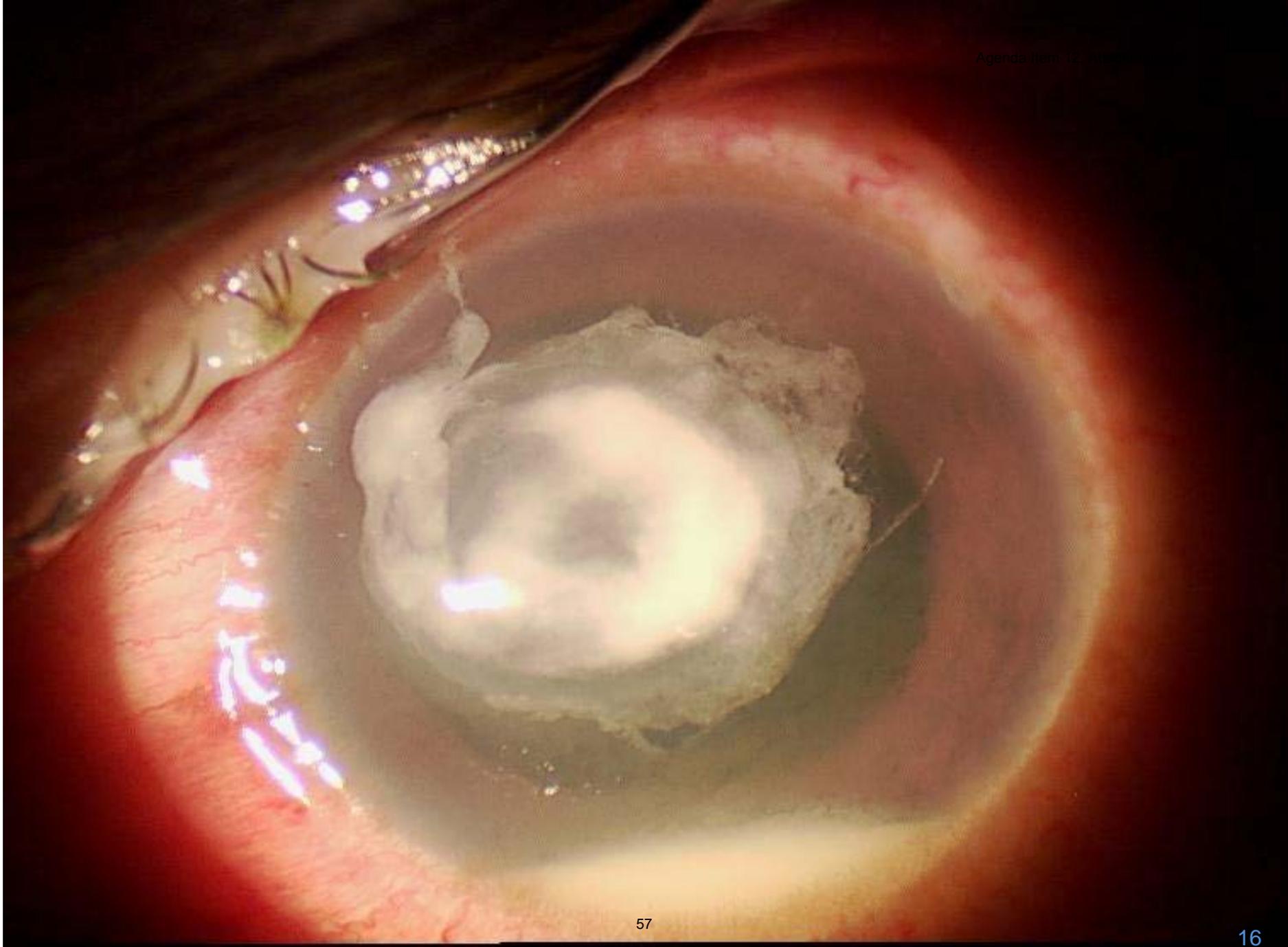
- 14 year old girl presented to her pediatrician with eye burning, pain, light sensitivity, and hand motion vision in left eye
- Wearing decorative lenses purchased from a video rental store
- No prior history of refractive error or eye disease
- On exam
 - eyelid swelling
 - copious purulent discharge

Case (cont.)

- 50% thinning of the cornea
- **Dx:** *Pseudomonas aeruginosa* corneal ulcer
- **Tx:**
 - Hospitalized for 4 days for hourly topical antibiotics
 - 9 months later scar and poor vision
 - Underwent penetrating keratoplasty (corneal transplant) to restore vision

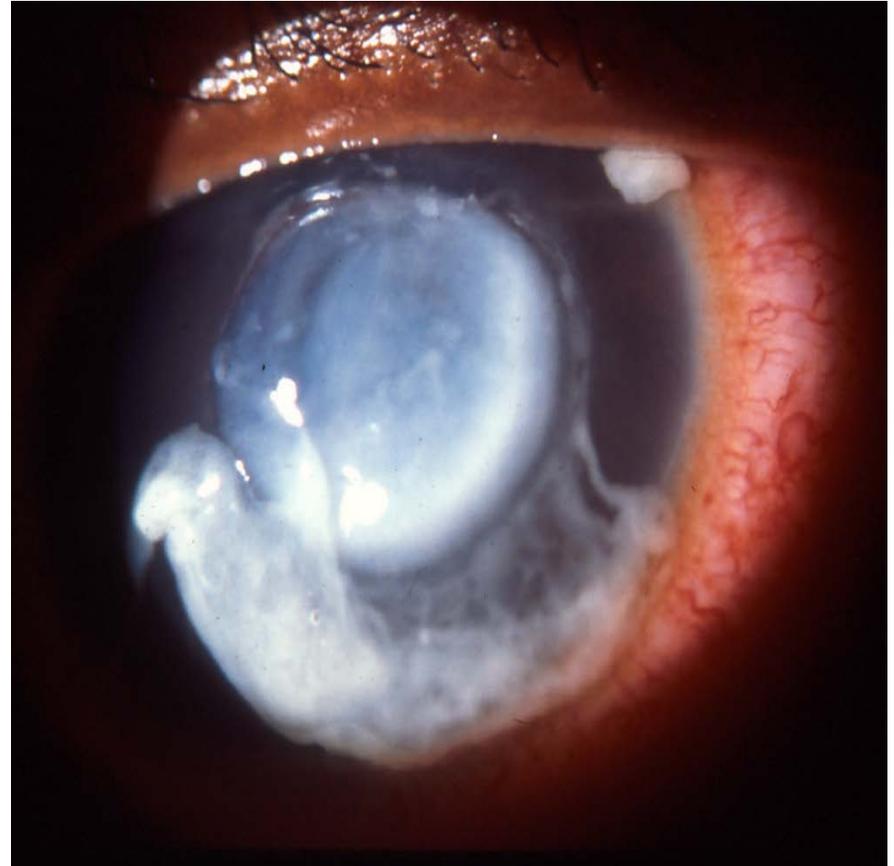


Courtesy of Timothy Steinemann, MD



Why Should I Care?

- Contact lenses are the leading cause of medical device-related emergency room visits (34,000 annually in U.S.)*
- Risk of microbial keratitis linked to internet/mail order-purchased lenses: 5x higher than those dispensed by eye care providers**
- ER physicians and pediatricians are often the first to see the patient



Courtesy of Tim Steinemann

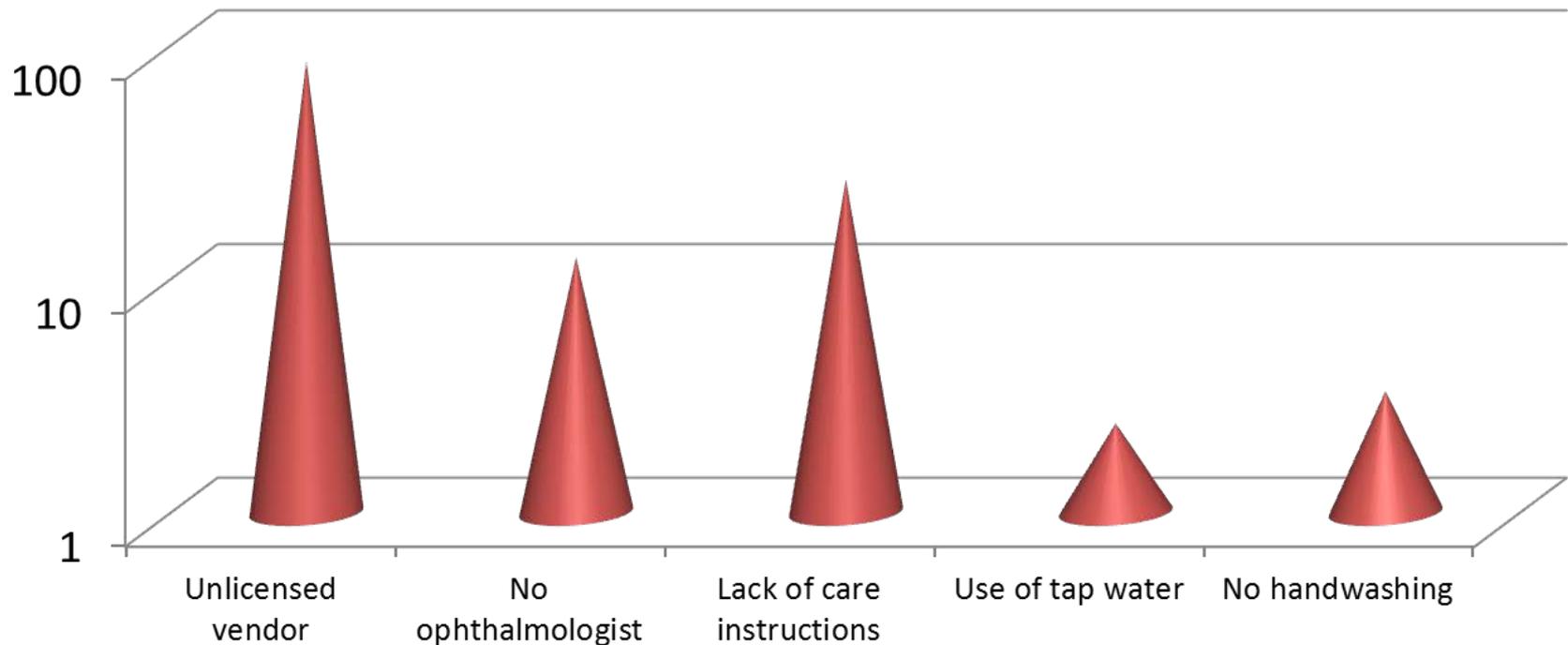
*C Wang et al. Pediatrics 2010; 126:247-59.

**F Stapleton et al. Ophthalmology 2008; 115:1655-62.



Risk Factors for Microbial Keratitis

Decorative Contact versus Non-Decorative Lens Wearers

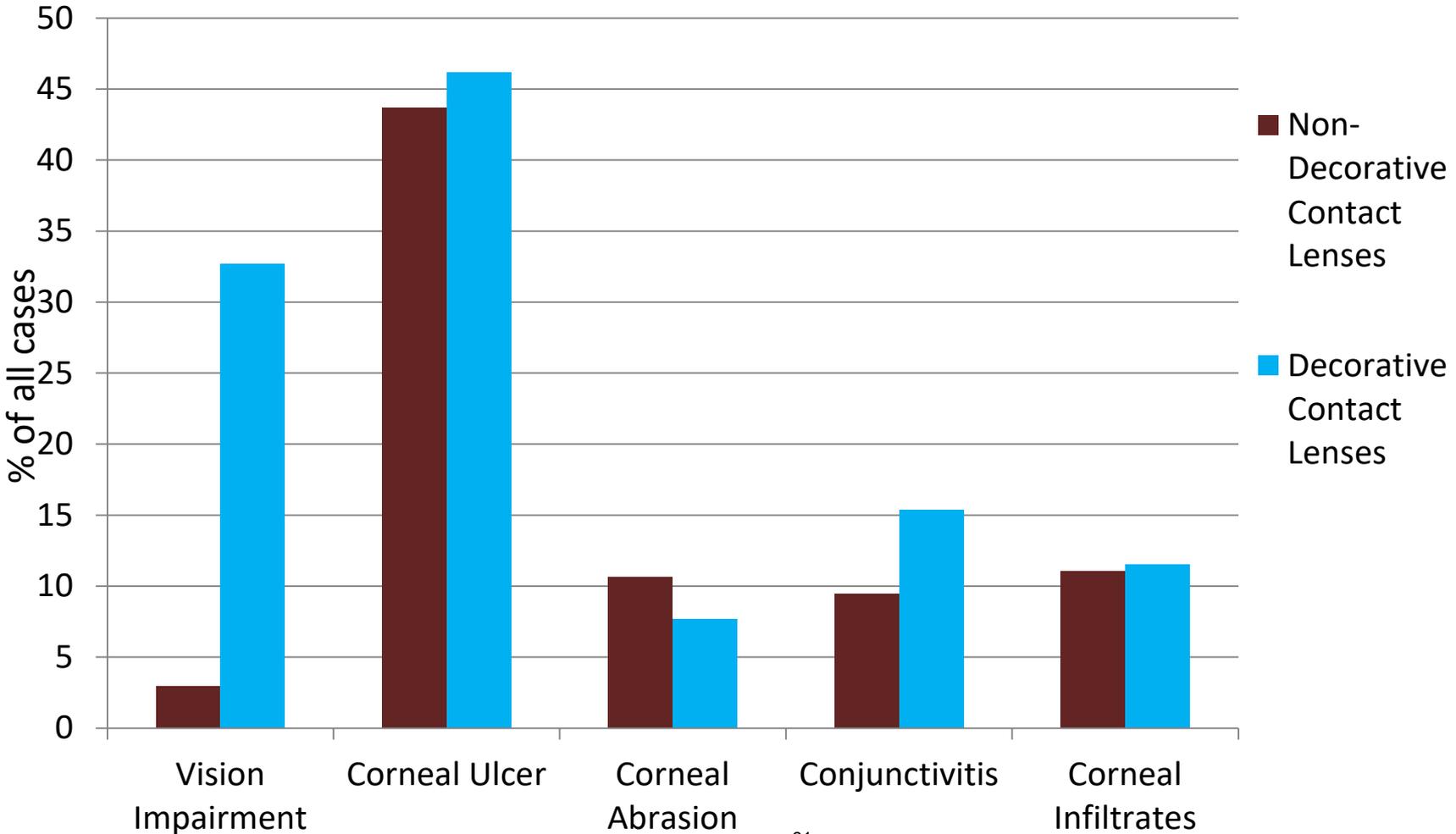


Why is the FDA Concerned about these Lenses ?

- The FDA has received numerous reports of corneal ulcers/microbial keratitis and blindness associated with some decorative contact lenses
- Most common groups affected are adolescents and young adults



Medical Device Reports (MDRs) from October 2011 to June 2015





Microbiological Testing

- FDA's Forensic Chemistry Center in Ohio tested nearly 350 decorative, non-corrective contact lenses.¹
- The results, [published in the *Journal of Forensic Sciences*](#), May 2017.
- Disturbing discoveries
 - Obtained without a prescription,
 - 285 purchased at novelty stores, tattoo parlors, import seizures, and the internet. These lenses were suspected to be counterfeit and unapproved.
 - Remaining 65 came from approved manufacturers.

1. Adrian D. Land, Katie L. Penno and Jennifer L. Brzezinski. [Identification of Microorganisms Isolated From Counterfeit and Unapproved Decorative Contact Lenses](#). *Journal of Forensic Sciences*. 24 MAY 2017, DOI: 10.1111/1556-4029.13553



Results of FDA Forensic Investigation

- Tested positive for microbial contamination
 - 60% (37/62) of the suspected counterfeit lenses,
 - 27% (61/233) of the unapproved lenses.
 - 3.7 % (2/54) of the authentic, approved contact lenses
 - According to study authors, 3.7% may be unusually high due to the small sample size.
- Results represent 29 different brands of counterfeit lenses
 - 14 (48%) had at least one of their contacts test positive for bacteria.
- Bacteria species are associated with serious eye problems
 - *B. cereus*
 - *Pseudomonas aeruginosa*

Other Reasons Why the FDA is Concerned about these Lenses

- Many individuals wear them solely as a fashion accessory
 - No professional fitting by eye provider
 - No training in wear and care
- Not all of these contact lenses have been evaluated by FDA
 - Manufacturing quality
 - Material composition



Are all Decorative Lenses the Same?

- There are cleared and approved decorative/cosmetic lenses that have been tested for safety and effectiveness and may have zero (0) power or correction in them
 - Cosmetic correction of injured eyes
 - Enhancement or change of eye color
- Many sold over the web or entering through our ports are not cleared or approved through FDA

Examples of Non-FDA Approved Lenses

- Hollywood Color Contacts
- Colores Nouveau
- Create Contact Lenses
- Colorfusion
- Total Colour
- Image Contact Lenses
- CIB Contact Lenses
- Disney Lenses
- Doll Eyes
- Eyetones
- Enhance Coloured Contacts
- Perfect Blends
- Halloween Contacts
- GEO Lens
- Colorvue
- Magic Color
- Magic Circle
- Dueba
- NEO
- Special Lens
- GEO Cosmetics
- GEO Flow Series
- GEO Circle Lens
- GEO Contacts
- Cool Lenses
- Rainbow
- Aura
- Urgan
- Ilusion
- Naturals
- Krazys
- Twilight
- Devil
- Barbie
- CO CO lenses
- Bella-GEO Lens
- Lolita, Cooleyes
- G&G

Examples of Websites Marketing Non-regulated, Non-FDA Approved/Cleared Decorative Lenses

- YouKnowIt.com
- BodyJewelleryShop.com
- Cheapestcolorcontacts.com
- The DollEye.com
- ColorContactsGalore.com
- Contactlens4less.com
- Contactsbay.com/store/cart.php
- EyeChange.com
- Geosupplier.blogspot.com
- IsakoBoutique.co.cc
- Online.Fantasyeyes.net
- PrettyandCute.com/store
- Buycoloredcontacts.net
- Dbeautyshop.com
- Foureyez.com
- Bcheap.com

Where is the Consumer Obtaining these Lenses?

- Retail Establishments
 - Beauty supply stores/ Beauty Salons
 - Flea Markets
 - Novelty Stores
 - Convenience Stores
 - Gas Stations
 - Street Vendors
 - Tanning Salons
 - Tattoo Parlors
 - Internet Sites
 - Mall Kiosks
 - Conventions (e.g., Comic-Con)
- Medical Suppliers
 - Internet Sites
 - Optical Shops
 - Pharmacies
 - Eye Care Providers



Regulators of Contact Lenses

- Food and Drug Administration (FDA)
 - Center for Devices and Radiological Health (CDRH)
 - Pre-market approval/clearance of lenses
 - Post-market surveillance
 - Center for Food Safety and Applied Nutrition (CFSAN)
 - Certification of color additives
- Federal Trade Commission
 - Sale and marketing of contact lenses



Actions FDA Has Taken to Protect Consumers

- Developed and implemented a communication strategy for consumers

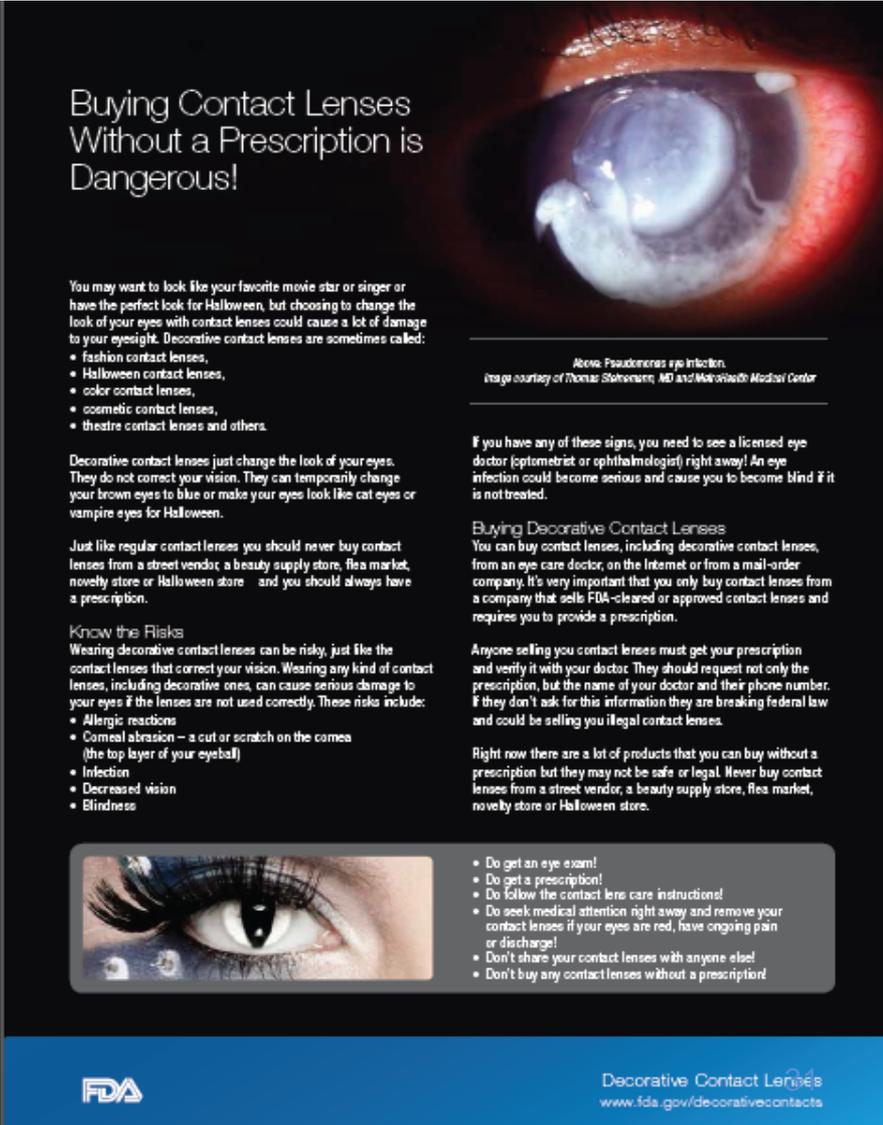
Communication Strategy - Website

- Developed comprehensive contact lens website with webpage devoted to use of decorative contact lenses
 - <http://www.fda.gov/contactlenses>
 - <http://www.fda.gov/decorativecontacts>
- Partnered with the CDC to create healthy contact lenses website with a webpage on decorative contact lenses
 - <http://www.cdc.gov/contactlenses/decorative-contacts.html>



Communication Strategy - Flyer

Developed a printable educational flyer posted on the decorative contact lens webpage



Buying Contact Lenses Without a Prescription is Dangerous!

You may want to look like your favorite movie star or singer or have the perfect look for Halloween, but choosing to change the look of your eyes with contact lenses could cause a lot of damage to your eyesight. Decorative contact lenses are sometimes called:

- fashion contact lenses,
- Halloween contact lenses,
- color contact lenses,
- cosmetic contact lenses,
- theatre contact lenses and others.

Decorative contact lenses just change the look of your eyes. They do not correct your vision. They can temporarily change your brown eyes to blue or make your eyes look like cat eyes or vampire eyes for Halloween.

Just like regular contact lenses you should never buy contact lenses from a street vendor, a beauty supply store, flea market, novelty store or Halloween store and you should always have a prescription.

Know the Risks
Wearing decorative contact lenses can be risky, just like the contact lenses that correct your vision. Wearing any kind of contact lenses, including decorative ones, can cause serious damage to your eyes if the lenses are not used correctly. These risks include:

- Allergic reactions
- Corneal abrasion – a cut or scratch on the cornea (the top layer of your eyeball)
- Infection
- Decreased vision
- Blindness

Buying Decorative Contact Lenses
You can buy contact lenses, including decorative contact lenses, from an eye care doctor, on the Internet or from a mail-order company. It's very important that you only buy contact lenses from a company that sells FDA-cleared or approved contact lenses and requires you to provide a prescription.

Anyone selling you contact lenses must get your prescription and verify it with your doctor. They should request not only the prescription, but the name of your doctor and their phone number. If they don't ask for this information they are breaking federal law and could be selling you illegal contact lenses.

Right now there are a lot of products that you can buy without a prescription but they may not be safe or legal. Never buy contact lenses from a street vendor, a beauty supply store, flea market, novelty store or Halloween store.

Do get an eye exam!
Do get a prescription!
Do follow the contact lens care instructions!
Do seek medical attention right away and remove your contact lenses if your eyes are red, have ongoing pain or discharge!
Don't share your contact lenses with anyone else!
Don't buy any contact lenses without a prescription!

Above: Pseudomonas eye infection.
Image courtesy of Thomas Stinson, MD and Malvern Health Medical Center

FDA

Decorative Contact Lenses
www.fda.gov/decorativecontacts



Communication Strategy - Consumer Update Articles

- **Consumer-focused articles distributed to over 75,000 subscribers**
 - "Decorative Contact Lenses: Is Your Vision Worth It?"
(<http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm275069.htm>)
 - "Improper Use of Decorative Contact Lenses May Haunt You"
(<http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048902.htm>)
 - "FDA Teams Up for Novel Campaign on Risks of Decorative Contact Lenses"
(<http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm402704.htm>)

Communication Strategy – FDA Video

- “Improper Use of Decorative Contact Lenses May Haunt You”

(<http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm187691.htm>)





Communication Strategy—Public Service Videos

- FDA partnered with American Optometric Association, the Entertainment Industries Council and artists from *American Horror Story* to create two public service videos
 - Informs on proper way to wear the lenses
 - Recommends getting an eye exam and valid prescription



Don't Lose Sight of Your Vision (Short Video)



Don't Lose Sight of Your Vision (Video)



Communication Strategy - Social Media

- (2012) Launched a Twitter Campaign targeting audiences of major meetings/conferences/movie releases featuring these lenses
 - Twilight Conferences (nationwide), Comic-Con, Hunger Games movie release, Chicago Comic & Entertainment Expo, Anime Boston
 - Sample messages:
 - Want to look like your favorite vampire? See an eye doctor before buying costume/fashion lenses. Link to flyer @twi_tour, #twilight
 - Don't risk your eyesight! See an eye doctor before buying costume/cosplay lenses. Link to flyer @c2e2 #c2e2
- FDA teamed with CDC's Contact Lens Health Week Twitter Chat in 2015 and 2016
- FDA launched a Google AdWords Campaign for a three-day time span in August 2015 during the CDC / FDA Twitter Chat



Communication Strategy—Medscape Articles

- “Telling the FDA: Why Contact Lens Adverse Events Matter”
 - <http://www.medscape.com/viewarticle/774062> 3
- “Decorative Contact Lenses: Truly Frightening”
 - <http://www.medscape.com/viewarticle/773106>



Actions FDA has Taken with Professional Organizations

- Collaborated with professional organizations for outreach to consumers and health care providers
 - American Academy of Pediatrics
 - American Academy of Ophthalmology
 - American Optometric Association
- Healthy Children article and AAP patient pamphlets
 - <https://www.healthychildren.org/English/health-issues/conditions/eyes/Pages/Decorative-Contact-Lenses.aspx>
 - <http://patiented.solutions.aap.org/handout.aspx?gbosid=156844>
- Educated eye professionals on how to recognize and report adverse events to FDA through MedWatch
 - http://www.aao.org/practice_mgmt/eyesmart/lenses.cfm
 - <http://www.aoa.org/x22305.xml>

Regulatory Actions FDA has Taken

- Issued import bulletins
 - Inform the port authorities about problems with imported goods

http://www.accessdata.fda.gov/cms_ia/importalert_1133.html
- Issued import alerts that have resulted in
 - Import detentions
 - Refusal and re-export of shipments

Regulatory Actions FDA has Taken

- FDA's Office of Criminal Investigation
 - Operation “Double Vision” in partnership with the US Immigration and Customs Enforcement and Homeland Security
 - Target illegal importation and distribution of counterfeit contact lenses
 - Seized more than 20,000 pairs of lenses
 - Operation “Cat Eyes” targeted Halloween stores
 - Charged 12 defendants in Los Angeles with illegal sale of misbranded and contaminated decorative and cosmetic contact lenses (maximum penalty 1 year federal prison & fines of \$100,000 to \$200,000)

US Attorney's Office – District of Nevada Federal Grand Jury

- Indicted a Las Vegas resident
 - one count of conspiracy to traffic in counterfeit goods and to introduce into interstate commerce misbranded devices;
 - four counts of trafficking in counterfeit goods;
 - and five counts of introducing misbranded devices into interstate commerce.
- Imported thousands of colored contact lenses from the People's Republic of China and South Korea
- Lenses bore counterfeit trademarks for CIBA Vision FreshLook COLORBLEND
- Customers complained directly to the seller about the quality of the contact lenses and questioned the seller about whether the contact lenses were genuine and FDA approved. Some of the contact lenses were tested and allegedly found to be contaminated with possibly hazardous bacteria.

Federal Trade Commission Actions

- The FTC has educational resources available online, such as:
 - **The Contact Lens Rule: A Guide for Prescribers and Sellers**, available at <http://business.ftc.gov/documents/bus62-contact-lens-rule-guide-prescribers-and-sellers>;
 - **Complying with the Contact Lens Rule**, available at <http://business.ftc.gov/documents/bus63-complying-contact-lens-rule>.
- Sends numerous warning letters and has had settlements regarding the sale of illegal lenses
- You may also contact the FTC's Division of Advertising Practices staff directly:
 - *1-877-FTC-HELP (1-877-382-4357)*
 - By mail to Federal Trade Commission, Division of Advertising Practices, Bureau of Consumer Protection, 600 Pennsylvania Ave., NW, NJ-3212, Washington, DC 20580
 - Online <https://www.ftccomplaintassistant.gov/#crnt>



How Can You Help?

- Submit and encourage MedWatch reports of any adverse events
 - <http://www.fda.gov/Safety/MedWatch/default.htm>
- Notify the Office of Compliance of illegal sales of contact lenses
 - <http://www.fda.gov/Safety/ReportProblem/ConsumerComplaintCoordinators/default.htm>
- Contact the Federal Trade Commission
- Disseminate this information to schools, health professionals, vendors and occupational licensing boards
 - Utilize your social media outlets
 - Link to FDA's website

Changes You May Wish to Make in Practice

1. For patients presenting with ocular symptoms, inquire about exposure to decorative lenses

2. Report infections and other poor visual outcomes to MedWatch (<http://www.fda.gov/Safety/MedWatch/default.htm>)

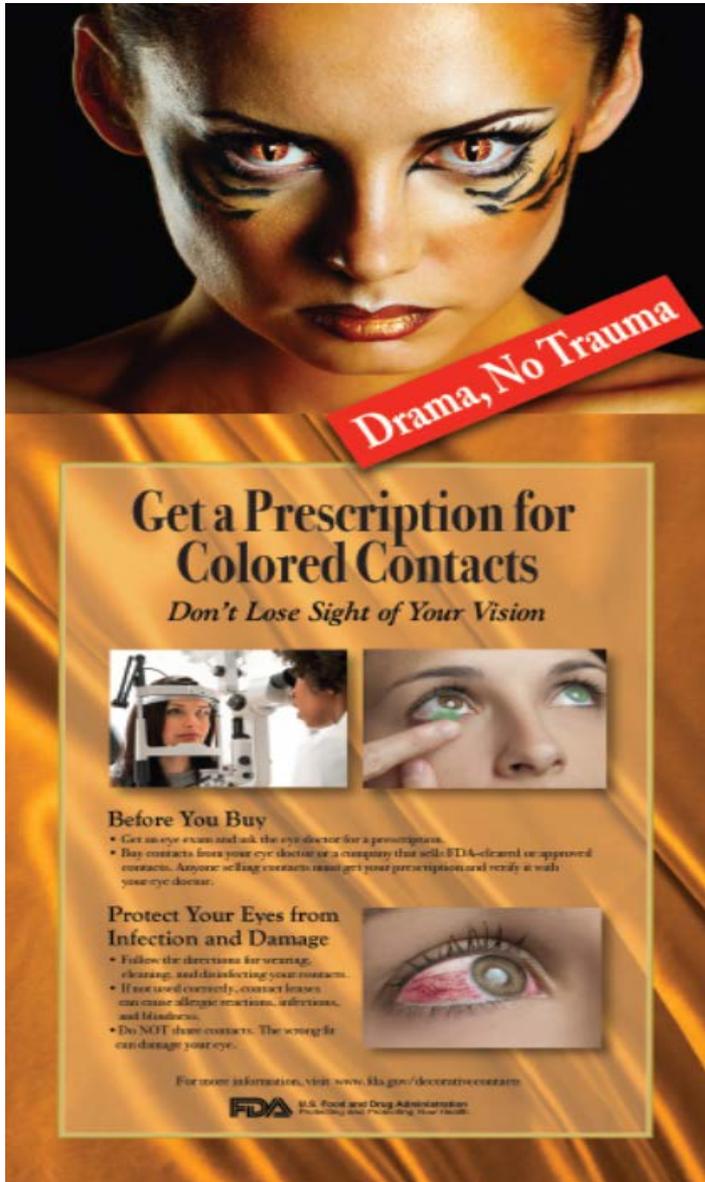
3. Report contact lens vendors selling without a prescription to the
 - Food and Drug Administration (<http://www.fda.gov/Safety/ReportaProblem/ucm059315.htm>)
 - The Federal Trade Commission (<https://www.ftccomplaintassistant.gov/#crnt&panel1-9>)

References

1. Food and Drug Administration Decorative Contact Lens Website—
<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/ContactLenses/ucm270953.htm>.
2. Federal Trade Commission Contact Lens Rule—
<https://www.ftc.gov/enforcement/rules/rulemaking-regulatory-reform-proceedings/contact-lens-rule>
3. TL Steinemann et al. *Over-the-counter decorative contact lenses: cosmetic or medical devices? A case series*. Eye & Contact Lens (2005) 31:194-200.
4. A Sauer et al. *Risk factors for contact lens-related microbial keratitis: A case control multicenter study*. Eye & Contact Lens (2015) epub.
5. Adrian D. Land, Katie L. Penno and Jennifer L. Brzezinski. Identification of Microorganisms Isolated From Counterfeit and Unapproved Decorative Contact Lenses. Journal of Forensic Sciences. 24 MAY 2017, DOI: 10.1111/1556-4029.13553

Special Thanks

- Michelle Tarver (FDA)
- Gene Hilmantel (FDA)
- Carol Clayton (FDA)
- Bonnie McGregor (FTC)
- Timothy Steinemann



Drama, No Trauma

Get a Prescription for Colored Contacts
Don't Lose Sight of Your Vision



Before You Buy

- Get an eye exam and ask the eye doctor for a prescription.
- Buy contacts from your eye doctor or a company that sells FDA-cleared or approved contacts. Anyone selling contacts must get your prescription and verify it with your eye doctor.

Protect Your Eyes from Infection and Damage

- Follow the directions for storage, cleaning, and disinfecting your contacts.
- If not used correctly, contact lenses can cause allergic reactions, infections, and blindness.
- Do NOT share contacts. The weight can damage your eye.



For more information, visit www.fda.gov/occolorcontacts

FDA U.S. Food and Drug Administration
 Protecting and Promoting Your Health



The NBEO would like to ask ARBO member boards to participate in this short survey. Please indicate your board's responses below to the following skills regarding the Part III Clinical Skills Examination (CSE) and the Injections Skills Exam (ISE). The NBEO sincerely appreciates your board taking the time to report invaluable feedback. All responses will be carefully evaluated and considered for potential future examination changes.

State:

1. Please circle "Keep" or "Replace" for each **Part III Clinical Skills Examinations** skill. The percentages represent the scoring weight for each skill in relation to the total examination.

Skill	Name	Weight	Keep	Replace
1	Case History/Patient Communication	7.60%	Keep	Replace
2	Patient Education	4.90%	Keep	Replace
3	Binocular Extraocular Muscle Motility Evaluation	3%	Keep	Replace
4	Static Peripheral Confrontation Visual Fields	2.90%	Keep	Replace
5	Near Cover Test and Near Point of Convergence	2.70%	Keep	Replace
6	Pupil Testing	4.60%	Keep	Replace
7	Blood Pressure Measurement	3.40%	Keep	Replace
8	Ophthalmic Lens Evaluation	3.50%	Keep	Replace
9	Biomicroscopy	8%	Keep	Replace
10	Goldmann Applanation Tonometry	6.20%	Keep	Replace
11	3-Mirror Gonioscopy	5.10%	Keep	Replace
12	Collagen Implant Insertion and Removal	3.30%	Keep	Replace
13	Soft and GP Contact Lens Insertion, Evaluation, and Removal	5.70%	Keep	Replace
14	Retinoscopy	5.40%	Keep	Replace
15	Distance Subjective Refraction	7.30%	Keep	Replace
16	Heterophoria and Vergence Testing at Distance	2.70%	Keep	Replace
17	Accommodation Testing	2.40%	Keep	Replace
18	Binocular Indirect Ophthalmoscopy	7.40%	Keep	Replace
19	Dilated Biomicroscopy and Non-Contact Fundus Lens Evaluation	7.60%	Keep	Replace
20	Injections	4.70%	Keep	Replace
	GENERAL ITEMS/Standardized Patient Scoring (affective communication)	1.60%	Keep	Replace

2. The NBEO is currently considering the addition of the following skills to the Part III Clinical Skills Examination. Please circle “Yes” or “No” if your board has an interest in adding each of the skills listed below.

Amsler Grid	Yes	No
Hertel Exophthalmometry	Yes	No
Cranial Nerves Assessment	Yes	No
Undilated 90D	Yes	No
Clinical Decision Making*	Yes	No

*Clinical Decision Making is an important element of the Part II PAM/TMOD examination. If implemented into Part III CSE it would involve the Standardized Patient giving the Candidate a diagnosis and asking the Candidate to verbalize their management plan.

3. Please list any additional skill(s) that your board would like to see included in the Part III Clinical Skills Examination.

4. Please circle “Include” or “Do Not Include” regarding which injections skills your board would prefer to see included in the **Injections Skills Examination (ISE)**?

Subcutaneous	Include	Do Not Include
Subconjunctival	Include	Do Not Include
Intramuscular	Include	Do Not Include
Intravenous	Include	Do Not Include

5. Should the Injections Skills Exam (ISE) be embedded within the Part III Clinical Skills Examination?

- A. Yes. Please explain _____
- B. No. Please explain _____
- C. Uncertain
- D. My board has no strong opinion regarding this matter.

6. Would your board support increasing the Injections Skills Exam attempt limit from 4 attempts to 6 attempts to draw blood during intravenous injection?

A. Yes. Please explain. _____

B. No. Please explain. _____

7. Please circle "Yes" or "No" regarding whether your board considers the ability or inability to draw blood on intravenous injection the most critical item in the skill?

A. Yes.

B. No.

If yes, should this ability or inability determine the overall pass vs failure on the Injections Skills Exam?

A. Yes.

B. No.

Exam Eligibility

8. Would your board support a limit on the number of attempts candidates have to pass NBEO examinations?

A. Yes If so, what attempt limit would you suggest? _____

B. No

Future Topics

9. What topics would be of interest to your board at the 2018 NBEO Workshop?
