The Evolution of Contact Lenses

(Home Study Course HS-18)

by

Anthony Record, DO
Optical Seminars, Inc.
PO Box 5445
Spring Hill, FL 34611-5445
homestudy@opticalseminars.com
© 2022 Anthony D. Record

Course Objectives

Upon completing this one-hour home study module, participants should:

- Have a deeper understanding of the history and development of contact lenses.
- Be able to understand how contact lenses evolved over the last 500 years.
- More effectively communicate with patients when it comes to contacts.
- Understand more fully the contents of the FCLCA
- Achieve a score of at least 70% on the 25-question Final Assessment.

The Evolution of Contact Lenses

by

Anthony D. Record, DO

Our timeline in the evolution of contact lenses begins in the year 1000 C.E. (For those old-school opticians participating in this module, C.E. is an abbreviation that stands for Common Era. It has all but replaced what you learned as A.D., which stands for Anno Domini – a Latin phrase that means "the year of the Lord." Likewise, B.C.E. stands for Before the Common Era, which has all but replaced B.C., which stands for Before Christ. Although these notations have been around for years, they have gained widespread preference since the late 20th century in a nod toward secularism and in deference to non-Christians. But alas, I digress. All future dates referenced in this module are obviously AD/CE.) And while we will only delve deeply into the dates regarding contact lenses, some *general* landmark dates are included simply for perspective.

1000 – Most timelines that highlight contact lenses begin with the next 16th century date (1508), but I feel compelled to begin here, 500 years earlier. Why? As the old aphorism reminds us, there is nothing new under the sun. Surely some forgotten, nameless man or woman stumbled upon the idea for contact lenses, long before Leonardo da Vinci (1452-1519) supposedly did in 1508.

1508 – In his 1508 *Codex of the Eye*, Leonardo thought about improving vision by submerging his head in a bowl of water! At least that's what I have always been told, and most every article or timeline on contact lenses mentions it. It is in Manual D of the *Codex* where he described a way of directly altering corneal power by submerging his eye in a bowl of water. Leonardo, however, did not suggest his idea be used for correcting vision or mention anything resembling a modern contact lens. Leonardo was more interested in learning about the mechanisms of accommodation of the eye. However, it is here in the 16th century that our 500-year journey begins.

1533 – King Henry VIII severs ties with the Catholic Church and declares himself head of the church in England.

1636 – Just over 100 years after Leonardo's water adventures, the French philosopher, mathematician, and scientist, Rene Descartes (1596-1650) appears on the optical timeline. While he was best remembered for the philosophical maxim Cogito Ego Sum – I Think, Therefore I

Am, Descartes is sometimes called the father of Western philosophy. Born in 1596, some time in 1836-1837, he developed an interest in vision and published a medical treatise in which he described a lens placed directly against the eye. Attached to the (contact) lens was a long tube of water, which we might infer was inspired by Leonardo's water-based musings. Of course, impracticalities existed with the Descartes lens/tube concoction because the glass tube holding the water prevented the wearer from blinking. Descartes was also the first to realize that the eye's cornea (and not the sclera) was the only section of the eye where light refractive manipulation was useful for vision correction. This contribution is almost a footnote in Descartes' legacy, as he is most widely regarded as the first modern philosopher. He is perhaps most remembered as having made an important connection between geometry and algebra, which allowed for the solving of geometrical problems by way of algebraic equations.

1685 – Apparently men of this era were not content to excel in one field alone. For instance, Philippe de la Hire (1640-1718) is described as a painter, mathematician, astronomer, architect, and scientist! It was in this year that he presented his dissertation on the Neutralization of the Cornea, and he also created drawings that illustrate how a concave lens placed on an eye could send light into the retina. It was by doing this he proposed a way of correcting myopia.

1769 – The first keratometer, used to measure the radius of curvature of the cornea was developed by Jesse Ramsden (1735-1800). Ramsden was a British mathematician who created instrumentation also used in the study of astronomy and general science.

1776 – On this date, in Philadelphia, 56 delegates sign the United States Declaration of Independence, which contains one of the most famous sentences in all of history: "We hold these truths to be self-evident, that all men are created equal, that they are endowed by their Creator with certain unalienable rights, that among these are Life, Liberty, and the Pursuit of Happiness."

1801 – It was in this year that Thomas Young (1773-1829), a British physician who made many contributions to the study of vision and light, put water into a small, convex lens with a wax collar around it. When he placed it against his eye, he noticed that it made him artificially nearsighted. Of course, his device was not practical, and it was unable to correct any specific vision problems. It would be another 44 years (1845) before the idea of using contact lenses to correct myopia, hyperopia, or astigmatism would be suggested. Young is also credited with discovering that it is the eye's crystalline lens (and not the cornea) that is responsible for accommodation. It was also in this year, that Young first described astigmatism. He also (correctly) theorized that color perception by humans was controlled by three different nerve fibers.

1823 – In this year, Sir John Herschel (1792-1871) created a description of what would be needed to make a contact lens. The English astronomer, chemist, and inventor believed that astigmatism was indeed caused by an irregularity of the cornea, and he conjectured that this could be corrected by applying a glass capsule filled with some sort of "animal jelly" against the cornea.

1845 – Herschel's theories were published in an article simply entitled *Light* in 1828, and the *Encyclopaedia Metropolitana* in 1845. He also mused if "an actual mold of the cornea might be taken" to correct for astigmatism. It would be 43 years more until the first "successful" contact lens fit is reported.

1861-1865 – The American Civil War is fought.

1884 – Although I have never seen this date included on a timeline regarding contact lenses, it is of monumental consequence. Remember, that it was nearly 40 years before that Sir John Herschel suggested that actual molds of the cornea might be taken. Until an 1884 invention, this idea was impractical at best. Why? Think about it. The cornea is totally avascular, with thousands of highly sensitive nerve endings. Imagine the pain involved in taking a mold of the cornea of a *living* human. But with this 1884 invention the problem was eliminated. The invention? Anesthesia.

1886 – The Statue of Liberty is dedicated in New York Harbor.

1888 – This year is considered a watershed moment in the history and development of contact lenses. It was in this year that our attention turns from the British to the German. In this year, while practicing in Zurich, Switzerland, German-born ophthalmologist Adolf Gaston Eugen Fick (1852-1937) is credited with inventing the contact lens. He tested the first lenses he designed on rabbits, then himself, and finally on a small group of human volunteers. The lenses were made of thin glass and fit over the entire surface of the eye. To make these lenses, Fick used plastic molds of actual human eyes, which he made from the plaster-cast molds of human cadavers. Because of the irritation they created Fick's lenses (which were 18-21 mm in diameter) could only be worn a few hours at a time. Fick would also try to mitigate the irritation problem by dabbing a bit of cocaine on his eyes to anesthetize them before lens insertion. Interestingly, there is a connection among Fick, Zeiss, and Ernst Abbe (most famous to opticians for Abbe Values).

Optician Timothy Bowden, FADO (1952-2017) writes about this connection in his article, *Contact Lenses – the Great Zeiss Secret.* "He [Fick] also approached Professor Ernst Abbe (1840-1905) at Carl Zeiss of Jena to grind some glass contact lenses [which he did]. These had a corneal curvature of 8mm radius and a small scleral band of 12mm radius. The firm of Carl Zeiss

had been founded in Jena in 1846. In 1866 Zeiss had engaged the services of Ernst Abbe, a lecturer and later professor of physics at Jena University. Initially Abbe was employed as a freelance researcher, but he became a full partner with Carl Zeiss in 1875. Abbe developed a much more scientific approach to the calculation of the optics of the optical instruments. In this same year a young chemist named Otto Schott was awarded his doctorate from the University of Jena. Abbe encouraged Schott to develop a more scientific approach in the making of glass. This led to the development of more than 100 different types of optical and industrial glass that surpassed any other glass previously available."

1888 – In the same year that all the developments of Fick and Abbe took place, a French ophthalmologist named Eugene Kalt (1861-1941) began using contact lenses to treat keratoconus. In a September 2012 article posted by Leandro Petalio at optometrystudents.com, he explains: "At about the same time, Dr. Eugene Kalt started to design lenses to place on the eye to correct the conditions of irregular astigmatism. Keratoconus is a corneal condition in which the cornea starts to develop a steep apex, causing irregular astigmatism. The idea was to vault the apex to its natural curvature. This treatment for keratoconus proved successful in improving vision and proved that contacts can correct vision. It was later realized that contact lenses could successfully correct a person's refractive error. Another individual by the name of August Muller (1864-1949) successfully corrected his own high myopia of 14 diopters using contact lenses. He wore the lenses himself and worked to create several molds of contact lenses by designing lenses with different curvatures to be applied to the eye. Muller is considered a pioneer in the manufacturing of contact lenses, and he was able to correct his 14D myopia to within 0.50D. The drawback for these early contact lenses was the material. It was not until 1934 when the introduction of PMMA plastic (polymethylmethacrylate) continued the evolution of contact lenses."

1911 – The Carl Zeiss Company produced an experimental, glass contact lens ground from solid glass to what they described as "a very high standard of optical precision."

1912 – Carl Zeiss introduced the very first contact lens trial set. They also produced glass, corneal contact lenses. In this year in Europe, nearly 2,000 contact lenses were manufactured – mostly all by Zeiss.

1914-1918 – World War I is fought.

1932 – Rowland Hill and John Crawford, a pair of British chemists, create a commercial synthesis of PMMA (polymethylmethacrylate), also known as plexiglass. It is half the weight of glass.

1933 – Josef Dallos (1905-1979) was born in Budapest, Hungary, and began working at a university ophthalmology clinic in 1928. He soon began fitting contact lenses using the Zeiss trial set. Dallos suggested some design improvements, and the newly designed lenses were jointly patented by him and Zeiss. He also received a Hungarian patent for contact lenses that were stabilized under the eyelids, but never actually touched the cornea. He also developed a molding technique from which the lenses were cast. Between 1937-1964 it is estimated that Dr. Dallos fitted nearly 7,000 patients with scleral lenses.

1939-1945 – World War II is fought.

1940 – An American-born optometrist, William Feinbloom (1904-1985) introduces the T-series of contact lenses. First developed in 1937, Feinbloom invented a combination glass and plastic contact lens. It had a glass optic zone, with a plastic carrier around the periphery. They were originally known as the U-series of lenses. Also, in 1937, Feinbloom received patents for the design of bifocal and trifocal scleral contact lenses. To this day, the Southern California College of Optometry makes an annual award to a student showing outstanding clinical patient care in Feinbloom's name.

1942 – The first ever textbook on contact lenses is written by Theo Obrig (1896-1967).

1948 – At last…an optician makes the timeline! Kevin Tuohy (1921-1968) was a California-based optician who worked at Solex Laboratories. Writing in *Review of Optometry* (July 20, 2007), Jack Scaeffer OD and Jan Beiting explain, "In 1948, Tuohy filed a patent for the first corneal contact lens, which was made entirely of PMMA. His discovery began as so many do - with a simple mistake. A scleral lens was accidentally lathed in two, leaving a smaller corneal button. Tuohy tried the damaged lens on himself to see what would happen. After more experimentation, he filed his patent and published a fitting manual for the new lenses. Optician Tuohy's contact lens was a large, thick, flat lens with blunt edges that would hardly be considered revolutionary today. But in the late 1940s, it marked a major shift from scleral to corneal contact lenses."

1949 – In 1946, about 50,000 pairs of contact lenses were sold in the United States. Due to Tuohy's design, that number increased to more than 200,000 lenses in 1949!

1950 – Oregon optometrist, George Butterfield (1895-1973), designed contact lenses using a curved, rather than a flat, corneal design. Among other things, this made it more difficult for the lens to accidentally pop off the eye.

1952 – HEMA (hydroxyethyl methacrylate) is developed. It is a polymer which made PMMA more comfortable. 1952 also saw the founding of the International Society of Contact Lens Specialists.

1960 – John F. Kennedy is the 35th President of the United States.

1961 – Otto Wichterle (1913-1998), was a Czech chemist, and is generally considered to be the inventor of soft contact lenses. In 1961, he produced the first usable soft contact lenses using a spin-casting process with parts from a Meccano set (Meccano is a building system that was the forerunner to American Erector sets.), on his kitchen table on Christmas day. Writing in *The Atlantic* (October 7, 2014), author Sarah Laskow explains: "He built a machine with a rotating mold out of his sons' toy construction set and a small motor. [Some accounts have it as his sons' bicycle motor, others as an engine from a gramophone. This one says he used the bicycle motor first and subbed in the gramophone's when scaling up the first model.] An early model of this contraption is on display at the International Library and Museum of Optometry, in St. Louis, Missouri. A license to produce these lenses was acquired by the National Patent Development Corporation and by Bausch & Lomb. After much research required by the FDA in the United States, the SOFLENS was launched in 1971. (An interesting video of Wichterle and his invention may be found on YouTube.)

In 1960, Wichterle described his work in *Nature*; in 1963, he patented it. The Czech government sold that patent to an American entrepreneur, and soft contact lenses went on to allow rom-com heroines during a makeover montage everywhere to shed their clunky glasses and to become, in a widely accepted sense, beautiful.

After his success, Wichterle was allowed to set up his own lab again, until in 1968, his participation in the Prague Spring lost him that one too. Almost 25 years later, after Czechoslovakia emerged from Communist rule and the Czech Republic was formed, he was again chosen to lead a scientific organization—the Academy of the Czech Republic. But, as the *Economist* noted when he died in 1998, even after his lenses were being used by millions of people, he 'always wore specs.'"

1966 – If you were to do a Google search for Walter Becker, no doubt you would be inundated with results dealing with one of the founding members of the rock band Steely Dan, who died in 2017. However, the Walter Becker on our timeline was a Pittsburgh optometrist who developed silicone, elastomer lenses, beginning in the mid-1950s. On January 11, 1966, Becker was granted

US Patent 3,288,741 for silicone, rubber-based contact lenses. In this same year (1966), Bausch and Lomb perfected a technique for casting hydrogel.

1968 – The FDA (Food and Drug Administration) classifies a contact lens as a drug.

1971 – March 18, saw the first commercial availability of soft, contact lenses. After years of development and a more than $18 million investment, Bausch and Lomb was finally granted FDA approval to bring their Soflens to market. They achieved sales of over $1 million in the first six months of their release.

1972 – Cooper Laboratories purchases Global Vison, forming CooperVision.

1973 – Soft, toric lenses first introduced in Australia and New Zealand.

1976 – The FDA reclassifies a contact lens as a medical device, not a drug. Bausch and Lomb is producing more than 25,000 contact lenses every day. The United States celebrates its 200-year Bicentennial.

1977 – Hydrocurve, soft toric lenses gained FDA approval, and became the first soft, toric lens available in the United States.

1981 – The FDA approved Permalens and Hydrocurve, the first contact lenses for cosmetic, 30-day extended wear correction of myopia.

1982 – Danalens launched in Denmark. Made by the MIA Lens Company, and invented by Dr. Michael Bay, it was the first disposable contact lens.

1983 – Vistakon (now Johnson & Johnson) bought the Stabilized Soft Lens Molding technology from Michael Bay.

1984 – Bausch and Lomb launched their Freshlens program for planned replacement, the first of its kind.

1986 – Wesley-Jessen produced the first colored, soft lens using a dot-matrix pattern. The FDA approves some gas-permeable lenses for overnight wear.

1987 – The Acuvue Disposalens was launched in Florida. The lenses came in six-packs and had a cost of about $10 per week.

1988 – The test in Florida is so successful that the Acuvue Disposalens was extended to the rest of the United States, and to Britain in September. The first version of soft, multifocal lenses is released.

1989 – Bausch and Lomb launched the Medalist lens – the first lens designed specifically as a daily wear, monthly disposable product. In this year the FDA decided to reduce approval of soft, extended-wear contacts from 30 days to 7 days.

1991 – The first soft, colored toric lens introduced by Wesley-Jessen.

1996 – Bausch and Lomb introduced the first disposable multifocal lens – Occasions Multifocal.

1997 – Acuvue, Surevue, and 1-Day Acuvue had a UV filter added to their polymer, as well as an "AV" inversion mark, to aid users in determining whether their contacts were ready to be placed on the cornea, or if they were inside-out.

1998 – Ciba Vision released the first contacts made of silicone hydrogel in the United States. The lens has the benefit of extremely high oxygen permeability. The Acuvue Bifocal is launched.

1999 – Several lenses (including Purevision and Ciba Night & Day) gain approval for 30-day continuous wear in the European Union. Acuvue 2 with "123" inversion marks and a UV filter are introduced. Wesley-Jessen launched Freshlook Colorblends.

2001 – Ciba launches Focus Daily Progressive lenses worldwide, the first daily, disposable progressive lenses. A year later, Ciba also launches the world's first daily disposable toric lenses.

2003 – The University of Florida announces the development of disposable contact lenses to disperse prescription drugs for glaucoma, infections, and other common eye problems. The FCLCA is signed into law by President George W. Bush.

2004 – Johnson and Johnson launched the 1-Day Acuvue Colors, the first daily disposable, colored lenses, and Acuvue Oasys silicone hydrogel lenses for weekly extended wear. B&L launched PureVision Toric, the silicone hydrogel toric.

On February 4, 2004, the FCLCA (The Fairness to Contact Lens Consumers Act) becomes a federal law. The Act mandates that eye care practitioners, including optometrists, automatically and without further fees, release contact lens prescriptions to their patients. It also requires contact lens sellers to verify the validity of contact lens prescriptions before releasing contact lenses to consumers. Because there is so much controversy regarding what the FCLCA does and does not do, and it is so important in guiding the sale of contact lenses, it appears here in its entirety:

SEC 1. 117 STAT. 2024 PUBLIC LAW 108–164—DEC. 6, 2003, Public Law 108–164 108th Congress An Act To provide for availability of contact lens prescriptions to patients, and for other purposes. Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, SECTION 1. SHORT TITLE. This Act may be cited as the ‘‘Fairness to Contact Lens Consumers Act’’.

SEC. 2. AVAILABILITY OF CONTACT LENS PRESCRIPTIONS TO PATIENTS. (a) IN GENERAL. —When a prescriber completes a contact lens fitting, the prescriber— (1) whether or not requested by the patient, shall provide to the patient a copy of the contact lens prescription; and (2) shall, as directed by any person designated to act on behalf of the patient, provide or verify the contact lens prescription by electronic or other means. (b) LIMITATIONS.—A prescriber may not— (1) require purchase of contact lenses from the prescriber or from another person as a condition of providing a copy of a prescription under subsection (a)(1) or (a)(2) or verification of a prescription under subsection (a)(2); (2) require payment in addition to, or as part of, the fee for an eye examination, fitting, and evaluation as a condition of providing a copy of a prescription under subsection (a)(1) or (a)(2) or verification of a prescription under subsection (a)(2); or (3) require the patient to sign a waiver or release as a condition of verifying or releasing a prescription.

SEC. 3. IMMEDIATE PAYMENT OF FEES IN LIMITED CIRCUMSTANCES. A prescriber may require payment of fees for an eye examination, fitting, and evaluation before the release of a contact lens prescription, but only if the prescriber requires immediate payment in the case of an examination that reveals no requirement for ophthalmic goods. For purposes of the preceding sentence, presentation of proof of insurance coverage for that service shall be deemed to be a payment.

SEC. 4. PRESCRIBER VERIFICATION. (a) PRESCRIPTION REQUIREMENT. —A seller may sell contact lenses only in accordance with a contact lens prescription for the patient that is— 15 USC 7603. 15 USC 7602. 15 USC 7601. 15 USC 7601 note. Fairness to Contact Lens

Consumers Act. Dec. 6, 2003 [H.R. 3140] VerDate 11-MAY-2000 23:33 Dec 22, 2003 Jkt 029139 PO 00164 Frm 00002 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL164.108 SUEP PsN: PUBL164 PUBLIC LAW 108–164—DEC. 6, 2003 117 STAT. 2025 (1) presented to the seller by the patient or prescriber directly or by facsimile; or (2) verified by direct communication. (b) RECORD REQUIREMENT.—A seller shall maintain a record of all direct communications referred to in subsection (a). (c) INFORMATION.—When seeking verification of a contact lens prescription, a seller shall provide the prescriber with the following information: (1) Patient's full name and address. (2) Contact lens power, manufacturer, base curve or appropriate designation, and diameter when appropriate. (3) Quantity of lenses ordered. (4) Date of patient request. (5) Date and time of verification request. (6) Name of contact person at seller's company, including facsimile and telephone number. (d) VERIFICATION EVENTS.—A prescription is verified under this Act only if one of the following occurs: (1) The prescriber confirms the prescription is accurate by direct communication with the seller. (2) The prescriber informs the seller that the prescription is inaccurate and provides the accurate prescription. (3) The prescriber fails to communicate with the seller within 8 business hours, or a similar time as defined by the Federal Trade Commission, after receiving from the seller the information described in subsection (c). (e) INVALID PRESCRIPTION.—If a prescriber informs a seller before the deadline under subsection (d)(3) that the contact lens prescription is inaccurate, expired, or otherwise invalid, the seller shall not fill the prescription. The prescriber shall specify the basis for the inaccuracy or invalidity of the prescription. If the prescription communicated by the seller to the prescriber is inaccurate, the prescriber shall correct it. (f) NO ALTERATION.—A seller may not alter a contact lens prescription. Notwithstanding the preceding sentence, if the same contact lens is manufactured by the same company and sold under multiple labels to individual providers, the seller may fill the prescription with a contact lens manufactured by that company under another label. (g) DIRECT COMMUNICATION.—As used in this section, the term ''direct communication'' includes communication by telephone, facsimile, or electronic mail.

SEC. 5. EXPIRATION OF CONTACT LENS PRESCRIPTIONS. (a) IN GENERAL.—A contact lens prescription shall expire— (1) on the date specified by the law of the State in which the prescription was written, if that date is one year or more after the issue date of the prescription; (2) not less than one year after the issue date of the prescription if such State law specifies no date or a date that is less than one year after the issue date of the prescription; or (3) notwithstanding paragraphs (1) and (2), on the date specified by the prescriber, if that date is based on the medical judgment of the prescriber with respect to the ocular health of the patient. 15 USC 7604. VerDate 11-MAY-2000 18:01 Dec 11, 2003 Jkt 029139 PO 00164 Frm 00003 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL164.108 SUEP PsN: PUBL164 117 STAT. 2026 PUBLIC LAW 108–164—DEC. 6, 2003 (b) SPECIAL RULES FOR PRESCRIPTIONS OF LESS THAN 1 YEAR.— If a prescription expires in less than 1 year, the reasons for the judgment referred to in subsection (a)(3) shall be documented in the patient's medical record. In no circumstance shall the prescription expiration date be less than the period of time recommended by the prescriber for a reexamination of the patient that is medically necessary. (c) DEFINITION.—As used in this section, the term ''issue date'' means the date on which the patient receives a copy of the prescription.

SEC. 6. CONTENT OF ADVERTISEMENTS AND OTHER REPRESENTATIONS. Any person that engages in the manufacture, processing, assembly, sale, offering for sale, or distribution of contact lenses may not represent, by advertisement, sales presentation, or otherwise, that contact lenses may be obtained without a prescription.

SEC. 7. PROHIBITION OF CERTAIN WAIVERS. A prescriber may not place on the prescription, or require the patient to sign, or deliver to the patient a form or notice waiving or disclaiming the liability or responsibility of the prescriber for the accuracy of the eye examination. The preceding sentence does not impose liability on a prescriber for the ophthalmic goods and services dispensed by another seller pursuant to the prescriber's correctly verified prescription.

SEC. 8. RULEMAKING BY FEDERAL TRADE COMMISSION. The Federal Trade Commission shall prescribe rules pursuant to section 18 of the Federal Trade Commission Act (15 U.S.C. 57a) to carry out this Act. Rules so prescribed shall be exempt from the requirements of the Magnuson-Moss Warranty—Federal Trade Commission Improvement Act (15 U.S.C. 2301 et seq.). Any such regulations shall be issued in accordance with section 553 of title 5, United States Code. The first rules under this section shall take effect not later than 180 days after the effective date of this Act.

SEC. 9. VIOLATIONS. (a) IN GENERAL.—Any violation of this Act or the rules required under section 8 shall be treated as a violation of a rule under section 18 of the Federal Trade Commission Act (15 U.S.C. 57a) regarding unfair or deceptive acts or practices. (b) ACTIONS BY THE COMMISSION.—The Federal Trade Commission shall enforce this Act in the same manner, by the same means, and with the same jurisdiction, powers, and duties as though all applicable terms and provisions of the Federal Trade Commission Act (15 U.S.C. 41 et seq.) were incorporated into and made a part of this Act.

SEC. 10. STUDY AND REPORT. (a) STUDY.—The Federal Trade Commission shall undertake a study to examine the strength of competition in the sale of prescription contact lenses. The study shall include an examination of the following issues: (1) Incidence of exclusive relationships between prescribers or sellers and contact lens manufacturers and the impact of such relationships on competition. 15 USC 7609. 15 USC 7608. Deadline. 15 USC 7607. 15 USC 7606. 15 USC 7605. VerDate 11-MAY-2000 18:01 Dec 11, 2003 Jkt 029139 PO 00164 Frm 00004 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL164.108 SUEP PsN: PUBL164 PUBLIC LAW 108–164—DEC. 6, 2003 117 STAT. 2027 (2) Difference between online and offline sellers of contact lenses, including price, access, and availability. (3) Incidence, if any, of contact lens prescriptions that specify brand name or custom labeled contact lenses, the reasons for the incidence, and the effect on consumers and competition. (4) The impact of the Federal Trade Commission eyeglasses rule (16 CFR 456 et seq.) on competition, the nature of the enforcement of the rule, and how such enforcement has impacted competition. (5) Any other issue that has an impact on competition in the sale of prescription contact lenses. (b) REPORT.—Not later than 12 months after the effective date of this Act, the Chairman of the Federal Trade Commission shall submit to the Congress a report of the study required by subsection (a).

SEC. 11. DEFINITIONS. As used in this Act: (1) CONTACT LENS FITTING.—The term ‘‘contact lens fitting’’ means the process that begins after the initial eye examination and ends when a successful fit has been achieved or, in the case of a renewal prescription, ends when the prescriber determines that no change in prescription is required, and such term may include—(A) an examination to determine lens specifications; (B) except in the case of a renewal of a prescription, an initial evaluation of the fit of the lens on the eye; and (C) medically necessary follow up examinations. (2) PRESCRIBER.—The term ‘‘prescriber’’ means, with respect to contact lens prescriptions, an ophthalmologist, optometrist, or other person permitted under State law to issue prescriptions for contact lenses in compliance with any applicable requirements established by the Food and Drug Administration. (3) CONTACT LENS PRESCRIPTION.—The term ‘‘contact lens prescription’’ means a prescription, issued in accordance with State and Federal law, that contains sufficient information for the complete and accurate filling of a prescription, including the following: (A) Name of the patient. (B) Date of examination. (C) Issue date and expiration date of prescription. (D) Name, postal address, telephone number, and facsimile telephone number of prescriber. (E) Power, material or manufacturer or both. (F) Base curve or appropriate designation. (G) Diameter, when appropriate. (H) In the case of a private label contact lens, name of manufacturer, trade name of private label brand, and, if applicable, trade name of equivalent brand name. 15 USC 7610. Deadline. VerDate 11-MAY-2000 18:01 Dec 11, 2003 Jkt 029139 PO 00164 Frm 00005 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL164.108 SUEP PsN: PUBL164 117 STAT. 2028 PUBLIC LAW 108–164—DEC. 6, 2003 LEGISLATIVE HISTORY—H.R. 3140: HOUSE REPORTS: No. 108–318 (Comm. on Energy and Commerce). CONGRESSIONAL RECORD, Vol. 149 (2003): Nov. 19, considered and passed House. Nov. 20, considered and passed Senate. Æ SEC. 12. EFFECTIVE DATE. This Act shall take effect 60 days after the date of the enactment of this Act. Approved December 6, 2003.

2005 – Acuvue Advance for Astigmatism launched in the United States.

2008 – Barack Obama is inaugurated as America’s first African-American president.

2009 – Ciba Vision launched Fresh Looks Dailies Colors. B&L launches the world’s first silicone hydrogel multifocal: PureVision Multifocal. Johnson & Johnson launched 1-Day Acuvue for Astigmatism.

2010 – Johnson & Johnson launched 1-Day Acuvue Moist for Astigmatism. J&J also received FDA approval for “the first and only silicone hydrogel daily disposable lens” in the United States: 1-Day Acuvue TruEye.

2011 – The Triggerfish device, made by Swiss-based manufacturer Sensimed, a contact lens for monitoring intraocular pressure, completes its first trial in the United States.

2012 – Bausch and Lomb launched Biotrue 1-day hypergel lenses with 78% water content. It is made with an outer surface designed to mimic the lipid layer of the tear film.

2013 – Researchers from Massachusetts Institute of Technology launched a contact lens which can release Latanaprost for the treatment of glaucoma over several weeks or months. The drug is contained in a film added to the periphery of the lens.

2014 – Google embarked on a project to test a "smart" contact lens that can monitor glucose levels in the tears of diabetes patients. The contact lens has a wireless chip and glucose sensor embedded between two layers of lens material, capable of testing glucose levels every second. They are also testing the possibility of adding an LED as a warning sign.

2015 – Alcon announced the release of Dailies Total 1 – the world's first water-gradient contact lenses. They feature an increase in water content from @ 30% at the lens' core to @80% at the lens surface, to nearly 100% at the outermost surface. An article in the January 2014 edition of *Contact Lens Spectrum* explains the benefit of the lens design: "The technology purports to endow the lens material itself with differential water content within different layers of the lenses. At the most superficial layer, the water content of a lens would be nearly 100% while the deepest layer much less so. This 'gradient' serves the purpose of improved dimensional stability at the corneal surface and improved wettability and comfort at the lens surface. The lids have almost no friction as the water content reaches 100%."

2016 – The FTC (Federal Trade Commission) proposes a change in the FCLCA. If finalized, this proposal would require contact lens prescribers to obtain a patient's signed acknowledgment of a document that must state:

"My eye care professional provided me with a copy of my contact lens prescription at the completion of my contact lens fitting, and I understand I am free to purchase contact lenses from the seller of my choice."

Prescribers would be required to keep a copy of this signed acknowledgement for a minimum of 3 years.

2018 – Though work on telescopic contact lenses has been going on for years, the technology seems to be on the verge of a true breakthrough. Author, Meriame Berboucha writes in *Forbes* magazine: "For the first time ever, an international collaboration of scientists, have created a

contact lens which can shift between magnified and normal vision. This advancement in contact lenses could offer those with retinal problems an unobtrusive solution.

One of the main problems these new contact lenses could solve is age-related macular degeneration (AMD). AMD is the loss of central vision caused by retinal damage that gets worse with age. Standard contact lenses aren't useful since they only correct for the eye's focus but cannot help with the fact that the retina is damaged. The current solution is to use bulky glasses that have mounted telescopes or surgical implants in the eye which help to magnify the light coming into the eye onto undamaged parts of the retina. Surgical implants are invasive and expensive, thus not ideal.

Instead, Eric Tremblay from the Ecole Polytechnique Fédérale de Lausanne (EPFL) in Switzerland and his team including scientists from the U.S, have designed a contact lens that consists of a telescope. The new contact lens is made of a plastic called polymethylmethacrylate (PMMA). It works by using tightly fitting mirror surfaces to make a telescope that fits within a space that is a millimeter thick. This fits within the contact lens and allows the lens to have a magnified mode and a normal mode. The normal mode is at the center of the lens and the magnified area is ring-shaped and at the edges of the contact lens. The telescope can achieve nearly 3X magnification. Tremblay says, 'A user can switch between normal and magnified vision…and to do this switching, you would use a pair of off-the-shelf 3D TV glasses that we have modified slightly.′ The glasses act as polarizers which can block either the magnified area or the normal area.

A prototype was made and tested with computer modelling and by creating a life-sized model of the eye. It was found that the magnified image was of greater quality than other magnification techniques. But before this becomes commercial Tremblay says some refinements need to be made. One of which includes using a material that is gas-permeable. PMMA is gas-impermeable so if this was used the eye would not be able to get oxygen, therefore they cannot be used for long-term wear. Tremblay says, 'We are now trying to build the lens using standard contact-lens materials that are gas-permeable…these will ensure that the cornea is receiving plenty of oxygen and so can be used safely all day long.' The team hope to see clinical trials being carried by the end of the year."

2019 – In 2018 it was announced that next year Acuvue will release in partnership with Transitions, a photochromic contact lens that also features UV and blue-light protection technology. Here is a description taken directly from the Acuvue website: "A first of its kind contact lens that provides wearers with vision correction and a dynamic photochromic filter that helps to continuously balance the amount of light entering the eye. These contact lenses quickly and seamlessly adjust from clear to dark in response to changing light conditions, reducing exposure to bright light indoors and outdoors, including filtering blue light and blocking UV rays. A range of everyday lighting situations, from artificial light to UV rays, may impact comfort and vision. Some people compensate for these harsh lighting environments by squinting, shielding their eyes, wearing sunglasses, or dimming lights. ACUVUE OASYS® with

Transitions® automatically adapt, helping the human eye manage different types of light and varying intensities of brightness throughout the day."

In December, COVID-19 begins to wreak havoc worldwide. Its effect on all ECPs and how they safely practice opticianry is monumental. As of December 2021, up to 800,000 deaths in the United States have been attributed t0 the virus.

2020 – In March, CooperVision released MiSight lenses in the United States. They are the first soft contact lenses designed to slow the progression of myopia in children 8-12 years old. The clinical success in slowing myopia is impressive. Check out one report here: https://www.eurekalert.org/news-releases/854700.

In August, Bausch and Lomb released its Infuse lenes – daily disposables made of silicone hydrogel.

2021 – Alcon released its Precision 1 for Astigmatism lenses. The lenses feature similar technology to its Total 1 water-gradient lenses. Also in 2021, the Federal Trade Commission amended the Fairness to Contact Lens Consumers Act. Last amended in December 2021, you may view the lates regulations here:

https://www.ecfr.gov/current/title-16/chapter-I/subchapter-C/part-315

2022 – Alcon plans to release its Total 30 lenses. One of the first reusable lenses released by any company in the last decade, they also feature the water-gradient technology and are designed to maintain their comfort and integrity for 30 days.

2023 – The sky is the limit!

Final Assessment

1. In what year did Bausch and Lomb introduce the first multifocal disposable lens?

    a. 1992
    b. 1994
    c. 1996
    d. 1998

2. Who was the first to realize that the cornea (and not the sclera) was the only section of the eye where light refractive manipulation was useful for vision correction?

    a. Leonardo da Vinci
    b. Michaelangelo
    c. Rene Descartes
    d. Otto Wichterle

3. The experimental telescopic lenses discussed in this module can achieve what degree of magnification?

    a. 3X
    b. 5X
    c. 7X
    d. 9X

4. Who was the Pittsburgh-based optometrist who began to develop silicone, rubber-based contact lenses?

    a. Walter Becker
    b. Donald Fagen
    c. Kevin Tuohy
    d. Otto Wichterle

5. Where does it state that anyone who sells contact lenses may not advertise that contact lenses may be obtained without a prescription?

    a. The FDA
    b. The FCLCA
    c. The NIH
    d. The CIBA Guide

6. Who was the first to think that "an actual mold of the cornea might be taken" to correct for astigmatism?

    a. Leonardo da Vinci
    b. Phillipe de la Hire
    c. Otto Wichterle
    d. Sir John Herschel

7. In what year was the International Society of Contact Lens Specialists founded?

    a. 1932
    b. 1942
    c. 1952
    d. 1962

8. Who made notations that some think refer to contact lenses in his *Codex of the Eye*?

    a. Leonardo da Vinci
    b. Rene Descartes
    c. Philippe de la Hire
    d. William Feinbloom

9. What is the main benefit of silicone hydrogel lenses?

    a. They are made of the thinnest material
    b. They allow more oxygen to reach the cornea
    c. They have the highest water content of any lens
    d. They allow for the flattest and steepest curvatures ever achieved

10. In what year did the FDA reclassify a contact lens as a medical device, not a drug?

    a. 1956
    b. 1966
    c. 1976
    d. 1986

11. The type of contact lens that has a water content that increases from its core to its surface is known as a:

    a. Silicone Hydrogel lens
    b. Gas-permeable lens
    c. Disposable lens
    d. Water-gradient lens

12. Which president signed the FCLCA into law?

    a. Bill Clinton
    b. George W. Bush
    c. Barack Obama
    d. Donald Trump

13. Who received a patent for contact lenses that were stabilized under the eyelids, but never actually made contact with the cornea?

    a. Josef Dallos
    b. William Feinbloom
    c. Rowland Hill
    d. John Crawford

14. Who filed a patent for the first corneal contact lens, which was made entirely of PMMA?

    a. John Crawford
    b. Kevin Tuohy
    c. Rowland Hill
    d. Josef Dallos

15. William Feinbloom was an:

a. Optician
b. Optometrist
c. Ophthalmologist
d. Osteopathic Physician

16. Kevin Tuohy was an:

a. Optician
b. Optometrist
c. Ophthalmologist
d. Osteopathic Physician

17. George Butterfield was an:

a. Optician
b. Optometrist
c. Ophthalmologist
d. Osteopathic Physician

18. Testing for contact lenses which dispensed drugs directly into the eye began at:

a. The University of Florida
b. Florida State University
c. The University of Central Florida
d. The University of South Florida

19. The FCLCA describes "Direct Communication" as communication by:

a. Mail or Fax
b. Telephone, Fax, or Electronic Mail
c. Telephone or Fax
d. Telephone only

20. The first textbook on contact lenses was written by:

a. Leonardo da Vinci
b. Rene Descartes
c. Theo Obrig
d. Brooks and Borish

21. The first ever disposable lenses were invented in:

a. Great Britain
b. Ireland
c. Switzerland
d. Denmark

22. Who is generally believed to be the inventor of soft contact lenses?

a. Otto Wichterle
b. Josef Dallos
c. Rene Descartes
d. Kevin Tuohy

23. In what year did William Feinbloom obtain patents for bifocal and trifocal scleral contact lenses?

a. 1927
b. 1937
c. 1947
d. 1957

24. What is the first contact lens designed to slow the progression of myopia in children?

a. MiSight by CooperVision
b. Infuse by Bausch and Lomb
c. Dailies Total 1 by Alcon
d. Acuvue Oasys with Hydrogel

25. Which contact lens company first released water-gradient contact lenses in the United States?

    a. Wesley-Jesssen
    b. CooperVision
    c. Bausch and Lomb
    d. Ciba Vision (Alcon)