Insights into the Contact Lens Industry: A Panel Discussion of Regulatory, Ethical, and FDA Issues

Mark A. Bullimore, PhD; Katie Gilbert-Spear, OD, JD, MPH;
Ashley Wallace Tucker, OD; Bret Andre, MS; Craig Norman, Moderator

January 19, 2024

I. Introduction of topic areas - Ethical Responsibility, Regulatory Issues, FDA concerns

- **a. Informed Consent in Contact Lenses**
  - i. Case Study and Practical Scenario
    1. Presentation real-life and/or hypothetical case study
       - a. Panelist discusses how informed consent was handled in this case.
  - ii. Informed Consent Slide Presentation
    1. Definition of informed consent
       - a. Importance of informed consent in optometry
    2. Key Ethical Issues
       - a. Full disclosure of information
       - b. What information should be disclosed?
       - c. Ensuring patients understand the information.
         - i. Decision-making capacity
       - d. Involving family or guardians when necessary
         - i. Avoiding coercion or pressure
         - ii. Discussing alternatives and risks
       - e. Documentation
         - i. Importance of keeping records of consent
         - ii. Discussing the role of written consent forms
    3. Challenges and Pitfalls
       - a. Identify common challenges in obtaining informed consent
       - b. Discuss potential pitfalls and how to avoid them
       - c. Strategies for effective communication with patients
  - iii. Panel Discussion
- **b. Contact Lens Patient Non-compliance**
  - i. Case Study and Practical Scenario
    1. Presentation of real-life and/or hypothetical case study
       - a. Panelist discusses how non-compliance was handled in this case.
  - ii. Patient Non-Compliance Slide Presentation
    1. Definition of non-compliance
       - a. Importance of addressing non-compliance in eyecare

b. The impact of non-compliance on patient outcomes and eyecare professionals

2. Key Ethical Issues
    a. Duty of care
        i. Ethical responsibility of eyecare professionals to ensure the well-being of their patients.
    b. Balancing patient autonomy and the responsibility to provide necessary care.
    c. Ensuring patients are fully informed about the risks and consequences of non-compliance.
    d. The importance of effective patient education and communication.
    e. Reasons for Patient Non-Compliance
        i. Lack of understanding
        ii. Financial constraints
        iii. Fear
        iv. Personal beliefs
3. Panel Discussion

c. Adverse Event Reporting

i. Case Study and Practical Scenario
    1. <u>Presentation of real-life and/or hypothetical case study</u>
        a. Panelist discusses how adverse event reporting was handled in this case.

ii. Patient Adverse Event Slide Presentation
    1. Defining Adverse Events in Contact Lens Wear
        a. Potential risks and consequences of contact lens-related issues
        b. Significance of reporting adverse events
    2. Ethical Responsibilities of ECPs
        a. Duty of care to patients
        b. Discuss the ethical obligation of optometrists to prioritize patient well-being.
        c. Address the importance of providing patients with information about potential risks.
        d. Professional integrity and honesty
            i. Highlight the ethical responsibility of being truthful about adverse events.
        e. Legal and Ethical Obligations
            i. Potential legal consequences of not reporting adverse events
        f. Reporting Mechanisms

3. Panel Discussion
    a. Adverse event reporting

d. Conflict of Interest

i. Case Study and Practical Scenario
    1. <u>Presentation real-life and/or hypothetical case study</u>
        a. Panelist discusses how conflict of interest was handled in this case.

ii. Conflict of Interest Slide Presentation
    1. Understanding Conflicts of Interest
        a. Define conflicts of interest
        b. Discuss how conflicts of interest can arise in patient care
        c. Highlight the potential impact of conflicts on patient trust and well-being
        d. Ethical Responsibilities of Optometrists
        e. Duty of care to patients
        f. Transparency and disclosure
            i. Address the importance of transparently disclosing potential conflicts of interest to patients.
    2. Types of Conflicts of Interest
        a. Financial conflicts
            i. Financial gain, such as selling eyewear or receiving commissions.
        b. Non-financial conflicts
            i. Personal relationships or professional affiliations.
        c. Identify other potential conflicts
        d. Ethical Decision-Making
            i. Transparency and Disclosure
                1. Explain the importance of transparently disclosing conflicts to patients
                2. Discuss when and how to disclose conflicts
            ii. Managing Conflicts of Interest
                1. Strategies for managing conflicts of interest in patient care
                2. Discuss potential safeguards and guidelines
                3. The role of practice policies and codes of ethics
    3. Panel Discussion

e. Telehealth and Telemedicine Regulations in Specialty Contact Lens Patient Care

i. Case Study and Practical Scenario
    a. <u>Presentation of real-life and/or hypothetical case study</u>
        a. Panelist discusses how telehealth was used in this case

ii. Telehealth Slide Presentation
    a. Definition of telehealth and telemedicine
        a. Current regulations
        b. Ethical responsibilities in maintaining patient safety and quality care
        c. Informed consent and patient education in a virtual setting
        d. Reimbursement models for telehealth services
    b. Panel Discussion

f. Product Recall and Safety Alert

i. Case Study and Practical Scenario
    a. Presentation of real-life and/or hypothetical case study
        a. Panelist discusses how the product recall was managed in this case
            i. Definition of product recall
            ii. Current regulations
            iii. Differentiating alerts from recalls
            iv. Manufacturer-Practitioner Communication
            v. Building effective communication channels
            vi. The role of transparency in collaboration
ii. Panel Discussion

g. Contact Lens Prescription Regulations: The Contact Lens Rule

i. Case Study and Practical Scenario
    a. Presentation of real-life and/or hypothetical case study
        a. Panelist discusses how the latest Contact Lens Rule impacts the patient and provider
        b. Fairness to Contact Lens Consumers Act
ii. Requirements
    a. Prescriber
    b. Seller
    c. What practices are not allowed
        a. Rx fulfillment
        b. Invalid Rx
        c. Altered Rx
        d. Suggestion that valid Rx is not needed
iii. Panel discussion

h. Off-label product use

i. Case Study and Practical Scenario
    a. Presentation of real-life and/or hypothetical case study
        a. What constitutes off-label use?
ii. Types of off-label use
    a. Therapeutic

b. Cosmetic
c. Comfort
d. Transparent communication with patients
e. Providing realistic outcomes and limitations
    a. Discussing potential risks and benefits
f. Legal, ethical and regulatory considerations

iii. Panel discussion

Summary and wrap-up