The FDA Bad Ad Program and Prescription Drug Promotion

Introduction

Welcome to the Food and Drug Administration's, or FDA's, online continuing education, or CE, credit course titled, "The FDA Bad Ad Program and Prescription Drug Promotion." During the next hour we will share information to help you make thoughtful and critical consideration of the drug information you get through prescription drug promotion. We'll also talk about how you can spot prescription drug promotion that may be false or misleading or raise other concerns and the important role that you can play in helping FDA ensure that prescription drug advertising and promotion is truthful and not misleading.

Target Audience

The target audience for this course is health care professionals including physicians, physician assistants, nurses, nurse practitioners, pharmacists, pharmacy technicians, and students. The course can be taken for informational purposes, for a certificate of completion for students, or for CE credit for health care professionals. At the end of the course you will be given the option to receive a certificate of completion or to obtain CE credit by registering using your credentials and, upon successful completion of an online assessment activity, a certificate for credit will be issued by your appropriate CE accrediting body.

Course Objectives

After completing the course, you will be able to:

- Identify the role that FDA's Office of Prescription Drug Promotion, or OPDP, plays in regulating prescription drug promotion and advertising
- Recognize persuasive techniques commonly used in advertising and promotion
- Describe the most common regulatory issues raised by prescription drug promotion
- Recognize potentially false or misleading prescription drug promotion
- Locate the Bad Ad contact information
- Translate knowledge into action and report potentially problematic prescription drug promotion to OPDP

Course Navigation

This course features many useful navigation features. Each screen includes:

- Hyperlinks to the FDA Web site and the Center for Drug Evaluation and Research, or CDER, Web page at the top left of the screen.
- A progress bar showing the current and total slide numbers for each module at the bottom of the screen.
- The current module number and title at the top right of the screen.

There are two menu options, which can be expanded or collapsed, located at the top of the screen: the Course Menu and Resources. The Course Menu tab accesses the Course Map, which lists all of the modules in the course. The outline can be expanded or collapsed, and each heading is hyperlinked for navigation.

Course Navigation

The Resources tab includes a link for Help, which displays instructions for using the course navigation features. There are hyperlinks to the FDA/Drugs, CDERLearn, and CDER OPDP Web pages, as well as a hyperlink to view FDA Compliance Examples in the form of Untitled and Warning Letters, some of which were issued as a result of Bad Ad complaints. The Common Drug Promotion Issues link accesses a document describing common regulatory issues regarding prescription drug promotion. Lastly, the Resources tab includes an email link for submitting any question you may have regarding this course to the FDA/CDER Office of Communication's Division of Drug Information, or DDI, and a Bad Ad email link and phone number for reporting potentially false or misleading or otherwise concerning promotional activities to the Bad Ad program office.

Course Navigation

The toolbar at the bottom of the screen features common navigation buttons, including:

- The Exit button, which closes the current module and pulls up the course map.
- The Pause/Play button, which halts and resumes playback.
- The CC button, which accesses closed captions.
- The Home button, which returns the user to the title page.
- The Back button, which returns the user to the previous page.
- The Next button, which advances playback to the next page.

Please note that all videos have their own navigation controls located at the bottom of each video window. These controls should be used to manage video playback and closed captioning.

The Bad Ad Program

It is important to note that Williams and Williams Pharmaceuticals is a fictional company and Declesau is a fictional drug. They were designed for this training program and are used for educational purposes only.

The Bad Ad Program

Pharmaceutical promotion is everywhere, from journal ads to webpages to social media to face-to-face sales calls to TV ads. When you think about the number of messages you are exposed to per day, per week, per year; it's staggering.

There are approximately 70,000 pharmaceutical sales reps working in the field today, making 8-10 calls per day, promoting 1 to 3 products per call. This means that anywhere from 145 million to 546 million promotional presentations are given per year. Add to that over 100,000 unique pieces of prescription drug promotional materials, such as journal ads, sales aids, and emails that are distributed to consumers and health care professionals, and the amount of messages aimed at informing and influencing you can be overwhelming.

Pharmaceutical companies can play an important role in disseminating information about prescription drugs, such as information about the availability of newly approved drugs and updated risk information about a particular drug.

Today we'll help you recognize persuasive techniques that are used in all kinds of advertising and promotion to help you be a better informed, more critical consumer of information. And we'll discuss how to analyze drug promotional materials so that you can discern false or misleading information from information that may be useful in your practice.

FDA Timeline

Before the 20th century, there were few laws regulating the content and sale of domestically produced drugs. Some state laws were drafted against unethical sales practices, but the growing pharmaceutical industry was largely unmonitored and unregulated. A wide range of medicines, tonics, elixirs, and fluid extracts were developed and marketed with extravagant claims of their curative powers. Some concoctions posed little health risk but were ineffective. Still, others posed a serious health risk to consumers.

In 1905, Collier's Weekly ran a series of 11 articles by Samuel Hopkins Adams entitled "The Great American Fraud," denouncing the patent-medicine industry for deceiving the public and hawking poisonous potions as cure-alls. Increasing public sentiment toward increased regulation in the food and drug industries led to President Roosevelt signing the Pure Food and Drugs Act of 1906. This law, among other things, prohibited the manufacture, sale, or transportation of poisonous patent medicines.

The FDA, however, still had serious challenges in its efforts to protect the public health. The 1906 Act was not stringent enough to prevent the sale of harmful products such as Banbar, a worthless "cure" for diabetes; or Radithor, a radium-containing tonic that sentenced users to a slow and painful death. Under the 1906 law, these products were still legal.

In 1937, tragedy struck. Over 100 people, many of them children, died following the treatment with Elixir Sulfanilamide, an untested formulation of Sulfanilamide that was highly toxic. The public outcry not only reshaped the drug provisions of a new law to prevent such an event from happening again, it helped push the bill through Congress. On June 25, 1938, President Franklin D. Roosevelt signed the Federal Food, Drug, and Cosmetic Act, which mandated that a drug be proven safe before it could be marketed and granted the FDA greater powers to regulate the industry.

In the early 1960s, a medical disaster abroad drew renewed public attention to the need for strong United States government oversight of drugs. In this case, Thalidomide, a sedative used for morning sickness, but never approved for use in the United States, caused tragic birth defects in thousands of newborns in other countries. Attention to the Thalidomide tragedy helped lead to passage of the 1962 Kefauver-Harris Amendments to the Federal Food, Drug, and Cosmetic Act, or FD&C Act, signed by President Kennedy. The 1962 Amendments mandated that drugs be proven effective as well as safe before they could be marketed, and gave the FDA tighter controls over drug trials. The 1962 amendments also gave FDA the authority to regulate prescription drug advertising, in addition to its authority over prescription drug labeling, which includes the package insert or PI. The prescription drug advertising regulations established as a result of the 1962 Amendments are detailed in the Code of Federal Regulations, section 202.1.

It is in part because of medical disasters like these that the FDA is tasked with assuring that all prescription and over-the-counter drugs are safe and effective.

In addition, in 1965, to ensure that the promotional practices of the past—wild, extravagant claims that provided false or misleading information—were not continued, FDA established the Medical Advertising Branch in the Division of Medical Review to monitor prescription drug advertising and promotion.

Now known as the Office of Prescription Drug Promotion, or OPDP, its mission is simple: to protect and promote public health by assuring prescription drug information is truthful, balanced, and accurately communicated. This is accomplished through a comprehensive surveillance, enforcement, and education program, and by fostering better communication of prescription drug labeling and its related promotional information to both health care professionals and consumers. While the promotion and advertising of prescription drugs is much improved from years past, there are still some instances of false or misleading promotion, or promotion that raises other regulatory concerns, so there is still work to be done.

The Bad Ad Program grew out of the office’s mission. Specifically, Bad Ad is the FDA's educational outreach program designed to educate the health care professionals to recognize potentially false or misleading prescription drug promotion and provide them with an easy way to report it to the agency.

Hi, I am Janet Woodcock, the Director of the Center for Drug Evaluation and Research, or CDER, at the Food and Drug Administration. Our mission at CDER is to ensure that the medicines you use, or will use, to treat your patients have been proven safe and effective. Another important part of our mission is ensuring that the information communicated to you by drug companies about these drugs is accurate and not misleading. After all, making treatment decisions based on the best available information benefits everyone. One way we accomplish this mission is through outreach programs like Bad Ad. By educating members of our health care community about misleading drug promotion and advertising and how to report it, we hope to improve the overall quality of information available to you about prescription drugs. Although the days of Banbar and Radithor are a distant memory, constant vigilance over the promotional claims of prescription drugs remains important for the safe and effective use of medicines. We hope this course provides you with a basic knowledge of the regulation of drug promotion and how to play a part, if you choose, in increasing the quality of prescription drug information available to you, your colleagues, and your patients.

Module 1: The FDA, Prescription Drug Promotion, And You – The Bad Ad Program

Bad Ad – What Is It?

The Bad Ad Program was created to serve as an awareness and outreach program to educate health care professionals about potentially false or misleading drug promotion and provide them an easy method to report it.

Bad Ad – Why Was It Created?

The Bad Ad Program was created to increase the effectiveness of FDA's Office of Prescription Drug Promotion, or OPDP's, surveillance program. OPDP's traditional regulatory activities primarily relied on reviewing promotional materials submitted to them by pharmaceutical companies; investigating complaints from industry, health care professionals, and consumers; and conducting risk-based field surveillance. While highly effective, OPDP was not able to observe drug promotion in settings such as physician offices, local dinner programs, or speaker presentations.

Bad Ad – Program Goals

Thus, the Bad Ad Program was established to raise awareness of the most common regulatory issues in health care professional-directed prescription drug promotion and serve as a way in which health care professionals can report suspected false or misleading drug promotion to the FDA. In this way FDA, in collaboration with concerned health care professionals, can ensure that prescription drug promotion is truthful and not misleading, wherever it may occur.

Bad Ad – How You Can Help

In order to help you recognize false or misleading promotion, we will discuss some of the most common issues a little later on in the course. The next step is to know how to report a promotional activity of concern. FDA has simplified the reporting process. All you need to do is send an email to badad@FDA.gov or call 855-RX-BADAD to submit a complaint. It's that easy. But before we get into that, we will first discuss some of the common persuasive techniques used in prescription drug promotion. It is important to note that these principles are not regulated by FDA, nor are these principles illegal or unethical. They are simply tools that any company can use to market and sell their products.

Module 2: The Science of Influence

The Science of Influence

Hi, I'm Dr. Linda Demaine. As you have studied the science of medicine, social psychologists including myself have studied the science of influence—how other people convince us to hold certain beliefs and opinions, and to act in certain ways.

If you've ever left a sales pitch with a new product and wondered: "Why did I buy that?" the science of influence can help solve the mystery. Certain elements of the sales context and certain things salespeople say can convince us to purchase products that we would otherwise refuse.

Over the next few minutes, I'll briefly describe some principles of persuasion that are relevant to marketing. Afterward, we'll go through a few scenarios that illustrate how companies may use these principles of influence to help sell their products.

So let's explore the science of influence.

While many factors can influence our behavior, I will focus on six well-documented principles of influence.

Dr. Robert Cialdini identified these six principles of influence, and researchers have tested these principles in many different contexts, where they've proven to be quite effective in shaping our behavior.

The first principle is SCARCITY. People want those things that are in limited supply. Things that are scarce are viewed as more attractive and more valuable - and we're willing to pay more and exert greater effort to obtain them. This principle underlies the value placed on rare versus common collectibles, for example. It's that difficult-to-find stamp, coin, or book that makes the collection, not the items that are more readily available. The scarcity principle also explains why limited-time offers are more enticing than the items for purchase inherently warrant. When the offer expires, the items may be gone for good, and we therefore desire to acquire them while we can.

The second principle is SOCIAL PROOF. We follow the lead of similar others - we look for evidence of what others who are similar to us are doing in a situation and do the same thing. After all, if other people are behaving in a particular way, it's probably the right way to behave. The social proof principle underlies, for example, our willingness to buy best-seller books or to try popular restaurants. Other persons consider these things worthwhile, and we're therefore inclined to experience them as well.

Dr. Cialdini's third principle of social influence is COMMITMENT AND CONSISTENCY. People want to be consistent with what they have already said or done. We must have had good reason to make those statements or do those things initially; the logic goes, so it makes sense to act consistently with them. This is why, for example, signing a petition in support of a political candidate or making a testimonial about a product causes us to subsequently be more willing to support that candidate or purchase that product. We've committed ourselves with that seemingly innocuous first step, and we're therefore more likely to agree to greater investments of our time and money that are consistent with our initial commitment.

The fourth principle is RECIPROCITY. People would be much less willing to help out one another if they thought that their good deeds would go unrewarded. And helping behavior keeps society strong. So as part of our socialization, we've been taught to give back to those who give to us. We are more likely to purchase a product, for example, after accepting a sample of it or accepting a small gift or favor - a bottle of water, the use of a telephone - from a salesperson. That person does something for us, and we feel obligated to do something for them in return - to buy what they are selling.

The fifth principle of social influence is AUTHORITY. People are more likely to take advice from those who are experts on a subject. We're more likely to believe the advice of an electrician about how to wire a lamp, for example, than we are to rely on the opinions of our friends who possess no extraordinary knowledge on the topic. Persons with expertise are more likely to accurately assess and respond to situations in their area of expertise, and it generally serves us well to follow them.

The last of Dr. Cialdini's principles is LIKING. People more often comply with requests made by those they like. Regardless of why we like someone - they're similar to us, they're physically attractive - people we like have a greater ability to influence our decisions and behaviors than do people for whom we have lower positive regard. Now you are familiar with the principles of influence. Later you will see how they apply to real life scenarios.

Module 3: FDA Oversight of Prescription Drug Promotion

Pharmaceutical Industry Drug Promotion – Prescription Drug Promotion

Pharmaceutical promotion is a multi-billion dollar industry – in 2017, pharmaceutical companies spent over 24 billion dollars promoting their drugs to health care professionals and consumers. As I am sure you are aware, the most visible and pervasive form of prescription drug promotion is direct-to-consumer promotion, such as television commercials, print ads, and internet-based promotion. These direct-to-consumer promotional communications, however, represent only a small percentage of the total prescription drug promotion budget.

Pharmaceutical Industry Drug Promotion – Prescription Drug Promotion

Spending by pharmaceutical companies to market prescription drugs directly to healthcare professionals actually outpaces spending on direct-to-consumer promotion by more than 3-to-1. In 2017 alone, the pharmaceutical industry spent over 18.5 billion dollars on journal ads, visual aids, web pages, emails, and various other promotions aimed specifically at healthcare professionals. Using these materials, pharmaceutical companies reach out to healthcare professionals in medical offices, hospitals, pharmacies, medical conferences, and industry-sponsored events.

Regulating Prescription Drug Promotion and Advertising – FDA Authority

Under the Federal Food Drug and Cosmetic Act, or FD&C Act, Congress gave FDA authority over prescription drug advertising and other promotion – both directly, through statutory provisions specifically addressing prescription drug advertising and labeling, and indirectly, through provisions addressing “intended use” of marketed drugs, and the requirements for FDA approval. Particular requirements apply to prescription drug promotion. Among these, prescription drug promotion must be consistent with FDA-required labeling, which includes the Package Insert. Furthermore, prescription drug promotion must present only truthful and non-misleading information that is appropriately supported. Prescription drug promotion must also present known risks associated with the drug along with the benefits.

Oversight of Prescription Drug Promotion

Prescription drug promotion can happen in many different venues and through various media. It may be carried out by a pharmaceutical company directly, or by others acting on their behalf. For example, prescription drug promotion may take the form of TV and radio advertisements, one-on-one interactions between sales representatives and healthcare professionals, speaker programs where a paid speaker is presenting on behalf of a pharmaceutical company, internet-based promotion, and many different kinds of written or printed materials.

FDA's Office of Prescription Drug Promotion monitors prescription drug promotion, regardless of the form, to ensure compliance with applicable legal requirements.

Oversight of Prescription Drug Promotion

It is important to note, however, that FDA's Office of Prescription Drug Promotion does not oversee the advertising and promotion of over-the-counter medications, dietary supplements, medical devices, compounded drugs, or prescription or over-the-counter drugs for animals. Promotion and advertising of these products are regulated by other groups in FDA or by the Federal Trade Commission.

Module 4: Common Drug Promotion Issues

Omission of Risk

Twyla Thompson, PharmD, Deputy Director, Office of Prescription Drug Promotion: Promotional materials that include claims regarding a drug's efficacy must also include information regarding the important risks associated with the drug that are included in the drug's Package Insert, including Black Box Warnings, which are the most serious warning a drug can have; contraindications; and warnings and precautions. So what does this mean for you? Well, let's say, for example, you are looking over a sales aid for a drug that you know has a Black Box Warning. This sales aid has pages and pages of information regarding the efficacy of the drug - how great the drug works - but, you notice that the Black Box Warning isn't presented anywhere in the sales aid. The lack of this important risk information from a sales aid that has numerous claims regarding the efficacy of the drug would be misleading - an omission of risk. Before we move on, it's important to note that this regulation regarding omission of risk applies to all prescription drugs, not just those with Black Box Warnings.

Minimization of Risk

CDR, Melinda McLawhorn, PharmD, MPH, BCPS, RAC, Team Leader, Office of Prescription Drug Promotion: When you are looking over a promotional piece, risk information must be presented with prominence and readability reasonably comparable to the presentation of efficacy information. Many factors can impact prominence and readability - for example, the style, size, and color of the font, layout of the piece, and the use of white space.

You can think of it like this - you are looking over a journal ad that presents efficacy claims in large, bold font with colorful graphics - the information really pops off the page. But the risk information, however, is buried all the way on the bottom of the page in tiny font with no headings or other signals to alert you to the presence of this important information. This format, in which the risk information is not presented with comparable prominence to the efficacy claims, minimizes the risks associated with the drug.

Overstating the Effectiveness

Christine Corser, PharmD, RAC, Health Science Policy Analyst, Office of Prescription Drug Promotion: Promotional materials would be considered false or misleading if, for example, they, one, overstate or exaggerate the effectiveness of a drug; two, make claims regarding the efficacy of the drug that aren't appropriately supported; or three, misrepresent data from clinical studies.

For example, let's say, during a sales call, a sales representative is promoting an antibiotic that we'll call DECLESAU. The sales representative shows you a flyer which contains the claim, "DECLESAU works in as little as 3 days." However, according to the Package Insert, the primary endpoint in the clinical trials used to support the approval of this drug was relief after 10 days, and there is no available data or evidence to support a shorter duration of treatment. Therefore, this claim misleadingly suggests that the drug works faster than what has been demonstrated.

Misbranding of an Investigational Drug

Nima Ossareh, PharmD, RAC, Regulatory Review Officer, Office of Prescription Drug Promotion: Under FDA regulations, if a sponsor represents in a promotional context that an investigational new drug is safe and effective for the uses under investigation or otherwise promotes the drug, when that drug has not been approved as a drug for any use, the investigational drug would be misbranded. This type of promotion may create a misleading impression regarding the usefulness and approval status of this product.

For example, let’s say DECLESAU is an investigational drug that is being studied for uses in treating complicated skin and skin structure infections and uncomplicated UTIs. DECLESAU has not been approved by the FDA for any use. However, a detail aid for the drug claims that DECLESAU is “an innovative treatment for complicated skin and skin structure infections and uncomplicated UTIs” and that “DECLESAU has demonstrated efficacy across a broad range of patients with a low rate of side effects.” These conclusory claims suggest, in a promotional context, that DECLESAU is safe and effective for treating complicated skin and skin structure infections and uncomplicated UTIs when it has not been approved as safe and effective for any use. Therefore, DECLESAU would be misbranded. The conclusions made in these claims may create a misleading impression regarding the usefulness and approval status of DECLESAU.

Misleading Drug Comparisons

Brian Tran, PharmD, MBA, Team Leader, Office of Prescription Drug Promotion: Claims or presentations in promotional materials that suggest that a drug is safer or more effective than another drug would be considered false or misleading if they are not appropriately supported. For example, you are attending a symposium and you stop by the promotional booth for DECLESAU. A bar chart on a convention panel at the booth compares study results from DECLESAU’s Package Insert and study results from its main competitor’s Package Insert and includes a claim stating that DECLESAU showed improvement in significantly more patients than its competitor. This comparison would be misleading because comparing the response rates for two different drugs in two different studies does not support a conclusion that one drug is safer or more effective than another because, for example, these studies may have been conducted in different patient populations or using different clinical study designs and methodologies.

Module 5: Prescription Drug Promotion: Real-Life Scenarios

Prescription Drug Promotion Scenarios

So, you’ve learned about persuasive techniques that marketers of all kinds can use to influence behavior. And you’ve learned about various common regulatory issues in prescription drug promotion.

Now, let's put your knowledge to the test using real-world scenarios. Throughout a Medical Park, healthcare professionals are coming face-to-face with drug advertising and promotion. Using the information that we just presented, can you correctly identify the potential regulatory issues in each scenario? Click on any one of the five locations, which include the emergency department, a Grand Rounds presentation, a break room, a pharmacy, and a doctor's office, to view these encounters. Make sure that you check out the Package Insert for the drug being promoted – you will find a link to this useful resource in the newspaper dispenser. Remember, the Package Insert is a valuable resource for important information about a prescription drug. Immediately following the video, you will be asked to choose the best answer to identify a common potential regulatory concern illustrated by the video. In addition, Dr. Demaine will point out the use of one or more principles of persuasion. Remember, if you experience anything similar to these scenarios, please report the incident to FDA's Office of Prescription Drug Promotion. FDA will evaluate each case to determine whether to investigate further or whether there appears to be evidence that the law has been violated. Alerting FDA about prescription drug promotion that you think raises concerns will help increase the quality of prescription drug promotion available to you, your colleagues, and your patients. Please note that the following scenarios are designed to highlight a specific regulatory issue. However, this issue may not be the only one presented in the scenario.

Doctor's Office

Sales Representative: Dr. Smith!

Dr. Smith: Oh hey, Jane. Hi, how are you doing?

Sales Representative: I'm good, how are you?

Dr. Smith: Good, good.

Sales Representative: Good to see you.

Dr. Smith: Nice to see you.

Sales Representative: How are the kids?

Dr. Smith: The kids are great. Sara is loving the new school and Nick was made captain of his volleyball team.

Sales Representative: Oh, you're kidding! That's wonderful! Congratulations.

Dr. Smith: Thank you, thank you.

Sales Representative: So, I just wanted to stop by today to give you some new and exciting information regarding DECLESAU. DECLESAU is now indicated for treatment of skin structure infections. As you know, DECLESAU is associated tendinitis and tendon ruptures, and exacerbation of myasthenia gravis, but this is more of a class effect and not really something to worry about. Personally I call on over 100 doctors, they prescribe DECLESAU all the time and none of them have seen these effects. I'm going to leave you with this brochure. It explains everything in more detail. Take a look at it. If you have any questions at all, give me a call.

Dr. Smith: Alright. Sounds good. Take care of yourself.

Sales Representative: Good to run into you today.

Dr. Smith: You too.

What did you just witness?

What did you just witness? A: Omitting Risk, B: Minimization of Risk, C: Overstating Effectiveness, D: Misbranding an Investigational Drug, or E: Misleading Drug Comparisons

Minimization of Risk

CDR. Melinda McLawhorn, PharmD, MPH, BCPS, Team Leader, Office of Prescription Drug Promotion: You just witnessed a drug representative minimizing the known risks of a prescription drug.

Specifically, the sales representative states that DECLESAU has Black Box Warning for tendinitis and tendon ruptures, and exacerbation of myasthenia gravis, but then goes on to minimize these risks by stating that it is more of a class effect and not really something to worry about. He even indicates that he calls on over 100 doctors and that none of them have seen these reported effects.

Dr. Linda Demaine J.D., PH.D: By the way, did you notice the use of the persuasive principles of Social Proof and Liking?

In this scenario, when the sales representative says to Dr. Smith that none of the 100 doctors he markets to have any concerns about the conditions described in the Black Box warnings - and thereby implies that Dr. Smith need not be concerned with them either -- he is using the principle of social proof. Remember, people are likely to follow the lead of similar others. Additionally, in this interaction, it is evident that the sales representative and Dr. Smith have a good rapport, consistent with the principal of liking. People whom we like are more able to influence our decisions and behaviors.

Grand Rounds

Sales Representative: Hi, and thank you all for coming to our promotional speaker program. Today we have the honor of having Dr. Kovac speak with us. As I am sure you all know, Dr. Kovac is one of the foremost experts on complicated skin and skin structure infections. He is here today to discuss an ongoing study with an investigational drug. And without further ado, Dr. Kovac.

(Dr. Kovac steps to the podium.)

Dr. Kovac: Good afternoon. Hi. I am here today on behalf of Williams & Williams Pharmaceutical to discuss a study for one of the company's pipeline products DECLESAU. As I'm sure you know, Williams & Williams is sponsoring a study of DECLESAU in use in patients suffering from complicated skin and skin structure infections. The study compares patients receiving DECLESAU with patients receiving traditional therapy. DECLESAU has proven to offer significant improvement when compared to the traditional therapy and with a highly effective cure rate, no added side effects, it is truly the next generation treatment option for patients with complicated skin and skin structure infections.

What did you just witness?

What did you just witness? A: Omitting Risk, B: Minimization of Risk, C: Overstating Effectiveness, D: Misbranding an Investigational Drug, or E: Misleading Drug Comparisons

Misbranding an Investigational Drug

Nima Ossareh, PharmD, RAC, Regulatory Review Officer, Office of Prescription Drug Promotion: In this last scenario, you witnessed a speaker, presenting on behalf of the company, suggest in a promotional context that an investigational drug is safe and effective for the use under investigation when the drug has not been approved for any use. The speaker, who is appearing as a representative of the drug's manufacturer, stated that DECLESAU has been proven to offer significant improvement compared to traditional therapy with a highly effective cure rate and no increase in side effects. He also stated that DECLESAU is the next generation treatment option for complicated skin and skin structure infections. However, DECLESAU, an investigational drug as noted by the sales representative, has not been approved as safe and effective for any use. The conclusions made in these claims may create a misleading impression regarding the usefulness and approval status of DECLESAU. Thus, the speaker's statements may prompt further investigation and could be presented as a piece of evidence in a misbranding case.

Dr. Linda Demaine J.D., PH.D.: Did you notice the use of the persuasive principle of Authority? As indicated in the scenario, Dr. Kovac is considered an authority in the field of infectious diseases. And, according to the authority principle, people are more likely to take advice from others who are considered experts in a subject, rather than someone who has little to no experience.

Sponsored Lunch

Sales Representative: So if you guys want to take your seats, we're going to start in just a second. Excuse me, excuse me. Hi. I hope that you all are enjoying your lunch today provided by Williams & Williams Pharmaceuticals. If you don't mind, I would just like to take just a couple minutes to talk to you about a new indication for DECLESAU. DECLESAU is now approved for the treatment of skin and skin structure infections caused by methicillin-susceptible S. Aureus, E. Coli, K. pneumoniae, or E. cloacae.

(The desktop placard reads: "The success rate for treatment of skin infection was incredibly high - 91 percent")

Sales Representative: Clinical studies performed in patients with skin infections demonstrated a 91 percent success rate. Now, DECLESAU is associated with black box warnings for tendonitis…

What did you just witness?

What did you just witness? A: Omitting Risk, B: Minimization of Risk, C: Overstating Effectiveness, D: Misbranding an Investigational Drug, or E: Misleading Drug Comparisons

Overstating the Effectiveness

LT. Christine Corser, PharmD, Health Science Policy Analyst, Office of Prescription Drug Promotion: This scenario highlighted a claim from a promotional piece that overstated the effectiveness of a prescription drug. Specifically, the promotional placard on the table states that DECLESAU has a success rate of 91 percent. However, the Package Insert states that DECLESAU has a success rate of 81 percent. Inflating the success rate by 10 percent overstates the efficacy of DECLESAU.

Dr. Linda Demaine J.D., PH.D.: Did you notice the use of the persuasive principle of Reciprocity?

In this scenario, the sales representative provided a free lunch. Gifts such as these cause us to be more likely to say "yes" to a request made by the person or company that provides them.

Break Room

PA Announcement: Attention. The memorial blood drive now taking place in room 237-B until 4pm today.

(Doctor grabs a medical journal from a rack of journals, and sits down to eat/drink and read. She flips through the journal and stops on a particular journal advertisement. The advertisement contains the following claims, “DECLESAU: Now approved for the treatment of skin infections! #1 Prescribed Antibiotic In Its Class.” The advertisement includes indications and common adverse reactions.)

PA Announcement: Paging Dr. Smith to trauma room 3. Dr. Smith to trauma room 3.

(Doctor tears out the journal ad, puts it in her pocket, and walks out the door.)

What did you just witness?

What did you just witness? A: Omitting Risk, B: Minimization of Risk, C: Overstating Effectiveness, D: Misbranding an Investigational Drug, or E: Misleading Drug Comparisons

Omitting Risk

Twyla Thompson, PharmD, Deputy Director, Office of Prescription Drug Promotion: The advertisement in the journal ad omits known risks of a prescription drug. The colorful, engaging print advertisement promotes the benefits of DECLESAU and mentions certain adverse reactions, but fails to include important information, including the Black Box Warnings, Contraindications, and Warnings and Precautions, regarding the risks associated with the drug.

Dr. Linda Demaine J.D., PH.D.: Did you notice the principle of Social Proof in the journal ad? Remember, social proof can be described as the following: we are more inclined to do what others similar to us are doing in a certain situation. In this journal ad, the claim, "#1 Prescribed Antibiotic in Its Class," communicates that many of this doctor's colleagues choose DECLESAU over other antibiotics.

Retail Pharmacy

(Sales Representative enters the pharmacy and walks up to window.)

Sales Representative: Hello. May I please speak to the Pharmacist on duty?

Pharmacy Tech: Of course, I will go and get her.

Sales Representative: Thank you.

(The pharmacy tech goes back into the pharmacy to get the pharmacist.)

Pharmacy Tech: Excuse me, doctor. There is someone here to see you.

Pharmacist: Be right there.

(The pharmacist finishes up and goes to the window.)

Pharmacist: Hello.

Sales Representative: Hi, how are you?

Pharmacist: Good, thanks. And you?

Sales Representative: I am great. Thank you. My name is Jane Crawford, I'm from Williams & Williams Pharmaceuticals.

Pharmacist: What can I do for you?

Sales Representative: Have you heard that DECLESAU is now indicated for the treatment of certain skin infections?

Pharmacist: I remember reading something about that. But there are already several fluoroquinolones on the market that are also used to treat skin infections, some even generic. I keep the ones I usually get orders for stocked on my shelves, but not the newer, pricier ones.

Sales Representative: It's true some older fluoroquinolones have generics and are cheaper. But DECLESAU has a much higher success rate in treating skin infections than the ones you stock on your shelf. As you can see by comparing the Package Insert for DECLESAU with the Package Insert for our biggest competitor, the efficacy rates in our clinical trials were much higher. That means doctors are going to prescribe DECLESAU over the other fluoroquinolones. Since patients can't really wait for their antibiotic to be delivered, you'll lose your customers to the pharmacy across the street that has DECLESAU in stock. So, can I count on you to stock DECLESAU?

Pharmacist: Yes, you make a good point. I will order some soon.

Sales Representative: Now, remember, DECLESAU is associated with boxed warnings for tendonitis…

What did you just witness?

What did you just witness? A: Omitting Risk, B: Minimization of Risk, C: Overstating Effectiveness, D: Misbranding an Investigational Drug, or E: Misleading Drug Comparisons

Misleading Drug Comparisons

Brian Tran, PharmD, MBA, Team Leader, Office of Prescription Drug Promotion: You just witnessed a misleading drug comparison - specifically, an unsubstantiated claim of superiority about a prescription drug. In this scenario, the drug rep claims that DECLESAU has a much higher success rate in treating skin infections than other fluoroquinolones on the market based solely on a comparison of the efficacy rates in the Package Insert for DECLESAU and the Package Insert for its biggest competitor. This Package Insert to Package Insert comparison is not enough to demonstrate DECLESAU's superiority over other fluoroquinolones, and the rep did not provide any other evidence, such as results from head-to-head studies comparing DECLESAU to other fluoroquinolones.

Dr. Linda Demaine J.D., PH.D.: By the way, did you notice the use of the persuasive principles of Scarcity and Commitment and Consistency? Recall that people want things that are in limited supply, and according to the sales rep, the pharmacist will likely miss out on the opportunity to stock DECLESAU unless he places an order for it soon. In addition, the sales representative, in asking if he could count on

the pharmacist to stock DECLESAU, and gaining the pharmacist's commitment, used the principle of commitment and consistency. As I indicated earlier, people generally act consistently with their previous statements or actions.

Module 6: Reporting Potential Drug Promotion Issues

Submitting a Complaint

So why should you tell FDA when you spot a potential regulatory issue with a prescription drug promotion? Well, in submitting a complaint to the Bad Ad Program, you can help protect public health by ensuring that the prescription drug information that both health care professionals and their patients use to help make treatment decisions is truthful and non-misleading.

Submitting a Complaint

Remember, submitting a complaint is easy. All you need to do is send an email to badad@FDA.gov, or call 855-RX-BADAD, describing the promotional activity of concern. We'll handle the rest. It's that simple.

Information to Include

Whether you call or submit an email, helpful information to include in the complaint is your name; the name of the drug; the name of the pharmaceutical company and/or representative involved, if applicable; day/time/place of the occurrence; and a brief description of the promotional activity, including the aspects that particularly concern you. You can even submit your complaint anonymously; however, complaints accompanied by names and contact information are helpful in cases where the FDA needs to follow up for more information.

OPDP Compliance & Enforcement

Once a complaint is submitted, the information you provide will be given to the Regulatory Review Officer in FDA's Office of Prescription Drug Promotion who is responsible for this class of drugs. It is important to note that all complaints are carefully reviewed. Now, this process does take time because FDA must be thorough in its investigation.

OPDP Compliance & Enforcement

During the investigation, the reviewer will evaluate each complaint and determine if it may serve as the basis for a potential compliance action or as valuable information for our ongoing surveillance activities. While every report of a possible regulatory issue serves to contribute to OPDP's surveillance activities, they will not all serve as the basis for compliance actions.

OPDP Compliance & Enforcement

When a Bad Ad complaint has been thoroughly investigated and FDA's Office of Prescription Drug Promotion believes the evidence shows that a legal requirement has been violated, FDA will take appropriate steps to address the promotion and ensure that the company complies with the law. FDA's compliance tools include issuing Untitled or Warning Letters.

OPDP Compliance & Enforcement

An Untitled letter notifies the company of the alleged violation and requests that they immediately stop misbranding their products by ceasing dissemination of all claims and presentations that are false or misleading, including all materials that would give rise to the same or similar violations as those identified in the letter.

OPDP Compliance & Enforcement

A Warning Letter also notifies the company of the alleged violation and requests that they perform the same actions as requested in an Untitled Letter, with the additional step of requesting that they correct the message in the promotional material by distributing new material that acknowledges the violation and provides truthful, balanced, and accurate information that is otherwise not misleading.

OPDP Compliance & Enforcement – FDA Actions

In addition, FDA, together with the Department of Justice, can bring enforcement actions in court, which may result in injunctions, consent decrees, product seizure, civil and criminal monetary penalties, and/or criminal prosecution. Reports sent to the Bad Ad program may also be used to help the Department of Justice with ongoing investigations into possible misbranding of prescription drugs.

OPDP Compliance & Enforcement – FDA Compliance Activities

As of 2018, the Bad Ad Program has received over 1500 reports of potentially false or misleading promotion, all of which have been thoroughly reviewed and investigated. In those cases where the appropriate evidence and standards were met and documentation was available, OPDP took action.

For example, the Diclegis Warning Letter resulted, in part, from several complaints to the Bad Ad program regarding a social media post by Kim Kardashian which presented various efficacy claims for Diclegis but failed to communicate any risk information or convey important limitations of use regarding the drug. In light of the potentially serious adverse public health impact of the violations, OPDP acted to prevent the misleading post from being more broadly disseminated by issuing a Warning Letter which subsequently resulted in the sponsor issuing a new post to correct the misleading messages.

The Afrezza Warning Letter was also based in part on a Bad Ad complaint regarding posts on the Afrezza Facebook page. Specifically, one of the posts on the page suggested that there were no safety concerns associated with the use of the drug. This was especially concerning from a public health perspective because Afrezza is a drug with multiple serious, potentially life-threatening risks, including a Boxed Warning. As a result, OPDP took action by issuing a Warning letter.

The Fycompa Untitled Letter resulted from a Bad Ad complaint regarding statements made by a sales representative to healthcare professionals during a lunch presentation. These statements misleadingly suggested that Fycompa was safe and effective for uses for which it was not approved, and for which its FDA-required labeling, which includes the Package Insert, did not provide adequate directions for use. This was especially concerning given the vulnerable pediatric population involved and the serious and life-threatening health risks associated with Fycompa.

These are just a few examples of some compliance actions that resulted from complaints submitted to the Bad Ad Program. For links to these and other examples of OPDP Warning Letter and Untitled Letters stemming from Bad Ad complaints, please click on the link provided under the Resources menu.

Module 7: Conclusion

Conclusion

FDA seeks to protect and promote the public health through its regulatory activities. FDA's Office of Prescription Drug Promotion supports this mission by assuring that prescription drug promotion is truthful, balanced, and accurately communicated. To that end, FDA's Bad Ad program was created to raise awareness in the medical community of potentially false or misleading or otherwise concerning promotion and encourage health care professionals to critically evaluate all the promotional messages to which they are exposed.

Conclusion

Together we can make a difference. As a health care professional, you can play an important role in ensuring that prescription drug advertising and promotion is truthful by recognizing and reporting any promotional activities of concern. If you believe you have witnessed a promotional activity of concern, please send an email to badad@FDA.gov, or call 855-RX-BADAD, and submit a complaint. We'll do the rest.

Credit/Certification

If you are a Health Care Professional and would like to receive CE credit for this course, please select the HCPs Online Test for CE Credit button to be linked to an online registration and graded assessment hosted by Amedco. You must register using your credentials and pass the online assessment in order to receive CE credit. Credit is available for physicians, physician assistants, nurse practitioners, nurses, pharmacists, and pharmacy technicians.

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