FDA'S ROLE IN ASPECTS OF DRUG ADVERTISEMENT AND LABELLING

A SMALL GUIDE FOR GETTING AROUND THE CONCEPTS OF PROMOTION, ADVERTISEMENT AND LABELLING FOR NEW DRUGS.

WHAT IS OPDP ?

OPDP (Office of Prescription Drug Promotion) is a wing of the USFDA (United States Food and Drug Administration) which is responsible for dealing with regulations related to the promotion of prescription drugs.

OPDP ensures the safety of the health of the public by ensuring the promotion of prescribed drug is truthful, balanced, and accurately communicated. This is achieved through compliance, research, comprehensive surveillance and by encouraging improved communication with labelling and promotional information to both healthcare personnel and to the public.

ROLE OF OPDP IN PRESCRIPTION DRUG ADVERTISING AND PROMOTIONAL ACTIVITIES

A) Reviewing promotional materials: The responsibility of OPDP reviewers is to analyze prescription medication advertising and promotional labels to ensure that the information presented in these promotional materials is not inaccurate or misleading.

B) **Conducting research:** OPDP performs prescription drug promotion research in order to better understand how promotional materials are used and how they affect consumers and healthcare professionals. This study assists OPDP in developing more effective regulatory tactics.

- C)ENFORCING THE LAW:
- OPDP may take enforcement action against companies that violate the FDA's prescription medication promotion requirements. This enforcement action could include letters of warning, fines, or criminal prosecution.
- This may include warning letters and actions to be undertaken under suitable sections in case of violations such as colossal fines, criminal liability, including a prison time.

D) **Post Market Monitoring:**
Even after a prescription drug has been approved and placed on the market, the OPDP continues to monitor promotional activities to verify that they comply with laws. If new safety information becomes available, the OPDP may mandate that promotional materials be updated to reflect the most recent evidence.

E) **OPDP provides guidance to the industry:** OPDP advises industry on how to comply with the FDA's prescription drug promotion standards. This guidance offers both broad ideas and specific instances of what constitutes truthful, balanced, and accurate advertising.

GUIDANCE AND CONTROLS ON ADVERTISING AND PROMOTION OF PRESCRIPTION DRUGS.

THE PRESCRIPTION DRUG ADVERTISING CODE OF FEDERAL REGULATIONS (CFR):

THE RULES ESTABLISHED INCLUDE THE FUNDAMENTAL REQUIREMENTS FOR PRESCRIPTION MEDICINE ADVERTISING, SUCH AS PROVIDING ACCURATE AND BALANCED INFORMATION ABOUT THE DRUG'S RISKS AND BENEFITS.

The Prescription Drug Advertising Code of Federal Regulations (CFR)

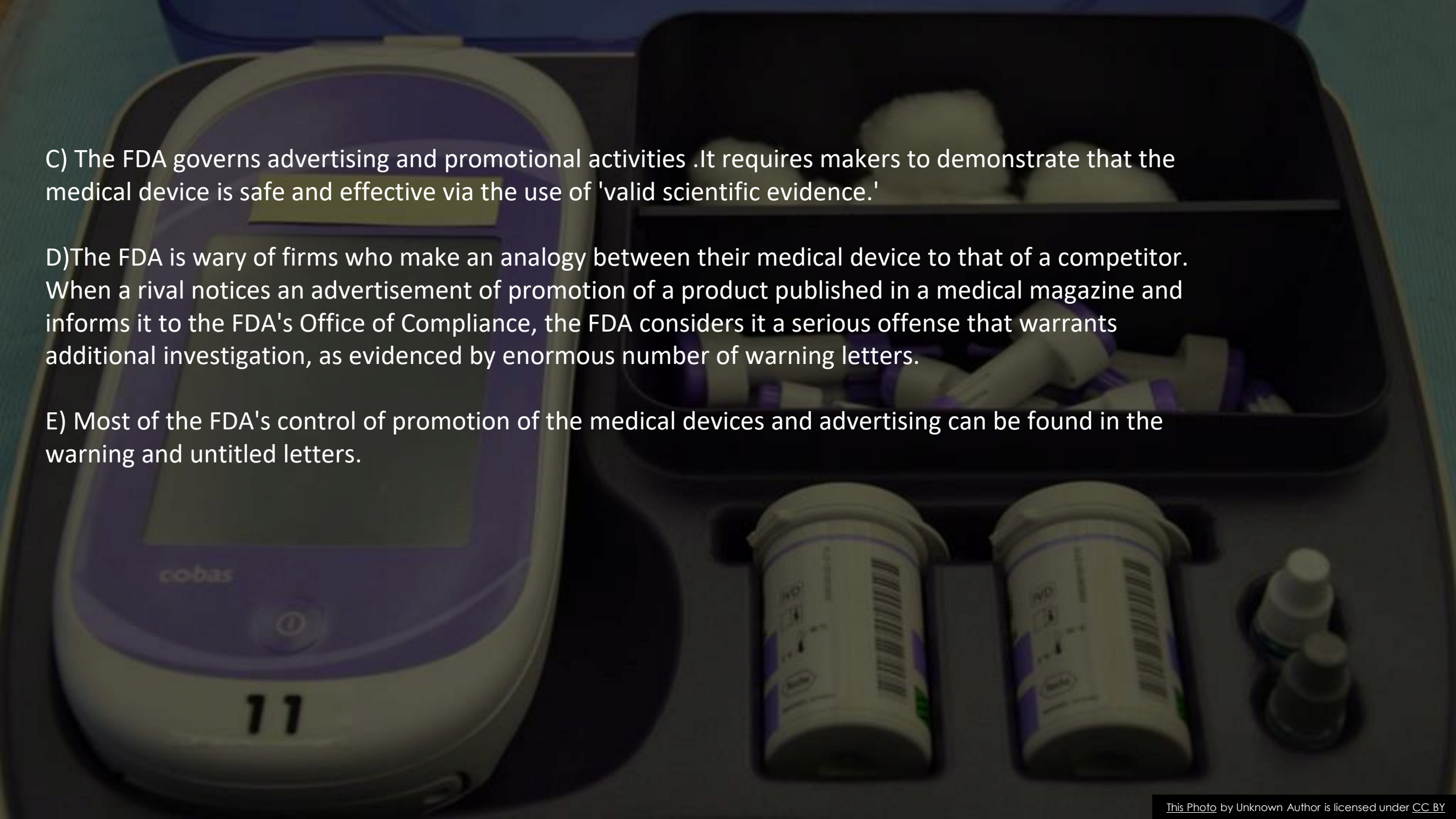
The rules established include the fundamental requirements for prescription medicine advertising, such as providing accurate and balanced information about the drug's risks and benefits.

A) Any information, including print, poster boards at scientific meetings, and video, must be consistent with the medical device or therapy's final product labeling, according to a principle governing authorized medical device advertising and promotion.

REGULATIONS

- B) SPECIFIC REGUALTIONS:
- 21 U.S.C. B' 352(q) provides that a restricted device is misbranded if its advertising is false and misleading in any particular way. This means that any statement made about the device in its advertising must be truthful and accurate.

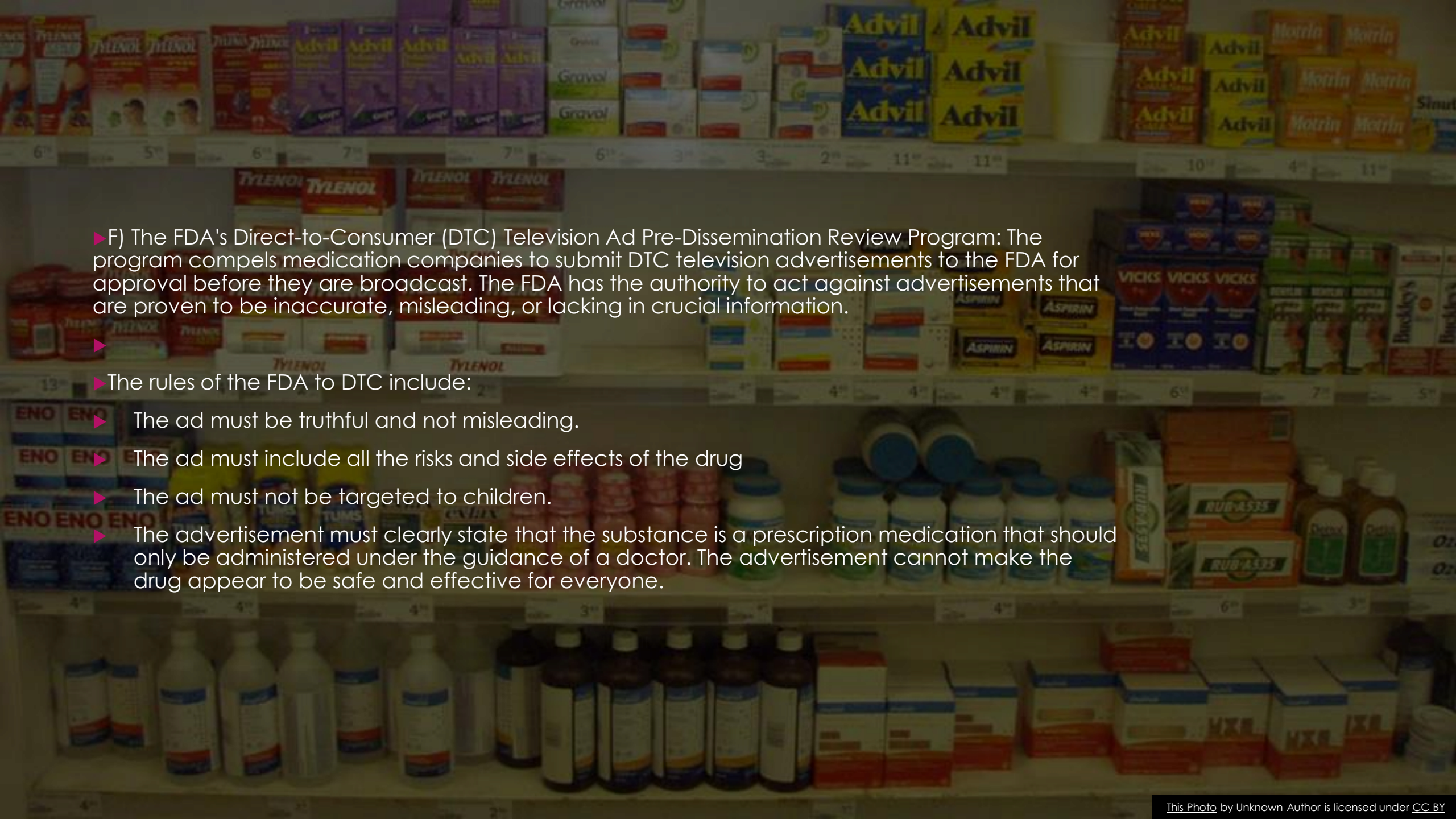
- 21 U.S.C. B' 352(r) provides that a restricted device is misbranded if its advertising does not contain a brief statement of the device's intended use and relevant warnings precautions, side effects and contraindications. This means that the advertising must include information about the device's intended use, as well as any potential risks associated with using the device.



C) The FDA governs advertising and promotional activities .It requires makers to demonstrate that the medical device is safe and effective via the use of 'valid scientific evidence.'

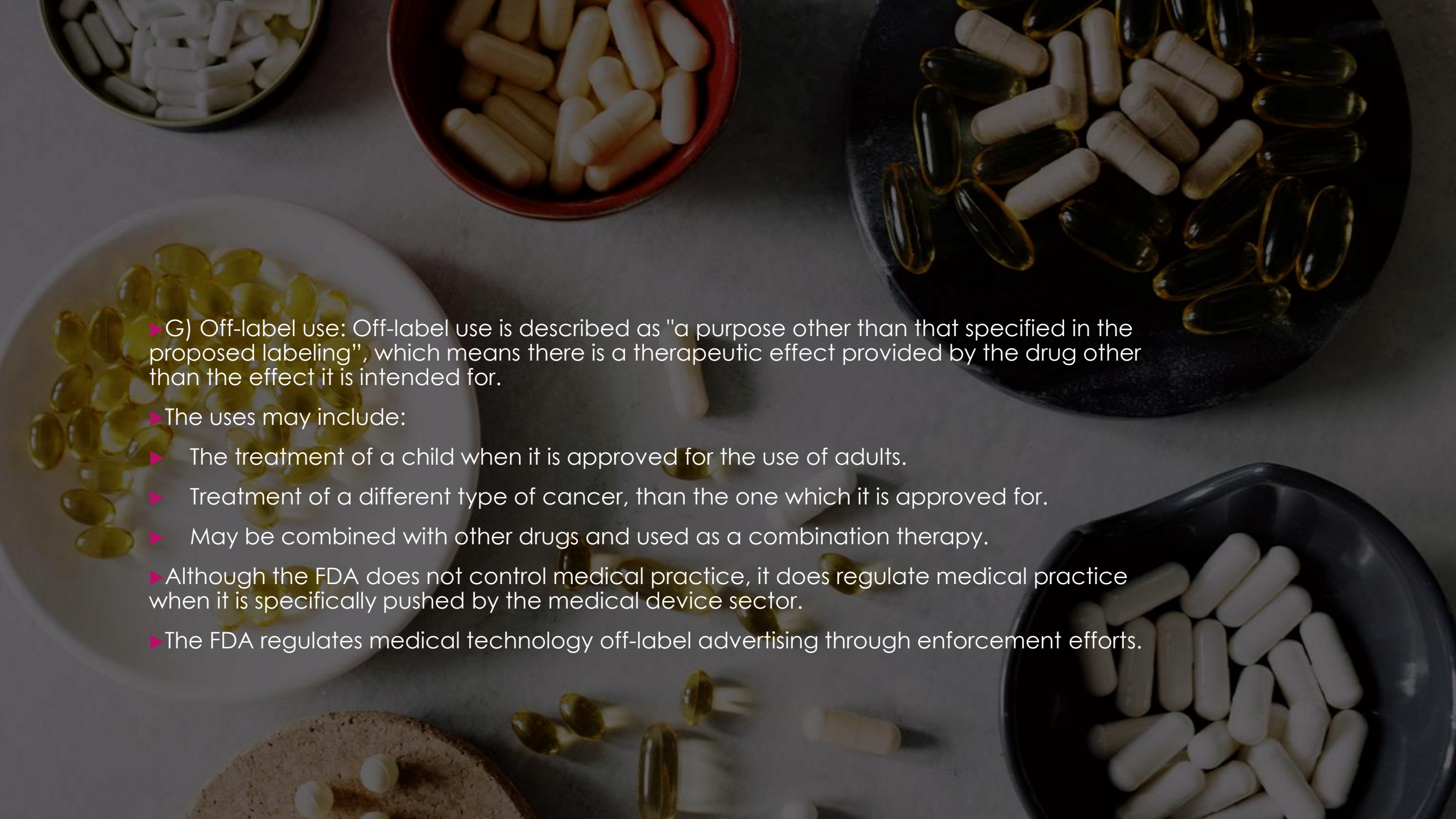
D)The FDA is wary of firms who make an analogy between their medical device to that of a competitor. When a rival notices an advertisement of promotion of a product published in a medical magazine and informs it to the FDA's Office of Compliance, the FDA considers it a serious offense that warrants additional investigation, as evidenced by enormous number of warning letters.

E) Most of the FDA's control of promotion of the medical devices and advertising can be found in the warning and untitled letters.



- F) The FDA's Direct-to-Consumer (DTC) Television Ad Pre-Dissemination Review Program: The program compels medication companies to submit DTC television advertisements to the FDA for approval before they are broadcast. The FDA has the authority to act against advertisements that are proven to be inaccurate, misleading, or lacking in crucial information.

- The rules of the FDA to DTC include:
  - The ad must be truthful and not misleading.
  - The ad must include all the risks and side effects of the drug
  - The ad must not be targeted to children.
  - The advertisement must clearly state that the substance is a prescription medication that should only be administered under the guidance of a doctor. The advertisement cannot make the drug appear to be safe and effective for everyone.



- G) Off-label use: Off-label use is described as "a purpose other than that specified in the proposed labeling", which means there is a therapeutic effect provided by the drug other than the effect it is intended for.
- The uses may include:
  - The treatment of a child when it is approved for the use of adults.
  - Treatment of a different type of cancer, than the one which it is approved for.
  - May be combined with other drugs and used as a combination therapy.
- Although the FDA does not control medical practice, it does regulate medical practice when it is specifically pushed by the medical device sector.
- The FDA regulates medical technology off-label advertising through enforcement efforts.

VARIOUS FORMS OF ADVERTISEMENTS

THERE ARE DIFFERENT REQUIREMENTS FOR PRESCRIPTION AND NON -PRESCRIPTION OR “OVER-THE-COUNTER” DRUGS.

PRODUCT CLAIM AD

A product claim ad names a drug, the condition it treats, and talks about both its benefits and risks. These ad's presents benefits and risks in a balanced manner. The ad should be such that it portrays both risks and benefits are shown to give a balanced impression of the drug. This style of advertisement is commonly used to marketing prescriptions, but it can also be used to promote over-the-counter medications, dietary supplements, and cosmetics.

PRODUCT CLAIM AD

DOS

1. Must identify the brand name or generic names of the drug.
2. The drug's FDA-approved use must be stated precisely.
3. Ads should mention that the drug can only be given by prescription.

DONTS

1. Ad should not make a claim which is not backed up by evidence or clinical experience.

2. Ad should not put prominence on the drug’s benefits than its risks.

3. Arbitraer is for use in adults 18 and older. Arbitraer is not for use in children.

PRODUCT CLAIM AD

DOS

4. The ad should provide the essential “fair balance” of benefits and risks information.

5. Ads must include a statement “you are encouraged to report negative side effects of prescription drugs to FDA”.

6. Inclusion of doctor’s advice about taking arbitraer.

7. Provide additional information, such as a website and telephone number (toll free).

DONT’S

4. The ads should not make false and misleading claims about arbitrary.

5. The ad should not present arbitrator’s risk in small type size and shouldn’t position the information nowhere near the benefits that are discussed.

REMINDER AD

A reminder ad mentions the drug's name, but it does not give any information about the drug's use. The premise of reminder ad's is that the audience know very well about the effects of the drug, and they need not to be educated again.

Reminder ads are generally used to promote mature stages of their life cycle. These ads can effectively improve brand awareness and boost the sales of the product.

REMINDER AD

DO'S

1. Reminder ad's must identify the drug's brand name and its generic name.

2. Should keep the ad short and on to the point.

3. Should state the approved uses of the drug.

DONT's

- The ad shouldn't describe the condition to which the drug treats.
- The ad should not make any dosage recommendations.
- Pictures showing impacts of drugs on their bodies should not be depicted and reminder ads are not allowed to suggest what the drug does.
- Misleading phrases are not allowed, they shouldn't mention who should take the drug and what the benefits of the drug are.

HELP SEEKING AD

A help-seeking ad describes a condition or a disease, but they do not recommend or suggest any specific drug. Although, they can provide information about the symptoms of a medical condition. Help seeking ads promote awareness and this helps people get the treatment they need. FDA does not regulate lawful help seeking ad's they are regulated by a different entity called Federal Trade Commission.

HEALTH SEEKING AD

DO'S

1. The ad identifies a problem and does not mention about specific drugs.
2. May recommend that the readers seek the advice of their healthcare provider.
3. The companies name should be mentioned.

DONT'S

1. The name of the specific drug should not be mentioned.

2. The text cannot be recommending a specific drug treatment.

3. Should not use testimonials from celebrities or public.

HELP SEEKING AD

DO'S

4. Directing the reader to ask a healthcare provider about symptoms is appropriate.

5. The telephone number to call or a website to visit for more information is mentioned.

DON'T'S

4. should not use images or videos which do not represent the drug.

5. Should not promote self-diagnosis or self-treatment.

COMMUNICATION OF RISKS AND BENEFITS OF THE DRUG

- There are certain regulations by the FDA, which necessitates the drug manufacturers to communicate the risks and benefits of drug in clear and easily understandable manner.

- It is essential to provide consumers with accurate and complete information about benefits and risks of a drug so that they can make an informed decision of taking it or not. The benefits and risks of drugs must be communicated in a way that is very easily understandable and is fair and balanced.

- This can be achieved by:
- Limiting the use of technical /medical terms that consumers may not understand.
- Using plain language summaries (PLS) to provide an overview of the drug's risks and benefits.
- Explaining the benefits and risks with the help of Images, charts, or graphs.
- Using truthful testimonials from real patients to help illustrate the benefits of the drug.
- Target-specific: The way you communicate about benefits and risks may vary with the individual, we should explain about risks and benefits according to the appropriate tone and language in which they understand.

STRATEGIES TO PROMOTE AND ADVERTISE A DRUG

IF I WERE TO BE AN OWNER OF A DRUG COMPANY, I WOULD PROPOSE THE FOLLOWING STRATEGIES TO PROMOTE AND ADVERTISE A DRUG

GAINING MARKET SHARE BY DISCOUNTS

- 1. This strategy helps to gain market share very easily in the initial stages of expansion.
- 2. Giving discounts is not only beneficial to the companies but also is useful for the consumers.
- 3. This promotes brand name and the publicity of the drugs.
- 4. As the drug attains popularity among the public, the company can gradually increase the price of the drug to cover the losses incurred during the cash burning initial discount stage.

BUILDING RELATIONSHIP WITH HEALTHCARE PROVIDERS

- Prescription medications are frequently under the control of healthcare providers. They make the decision whether or not to prescribe a medication to their patients. It is beneficial to cultivate good relationships with healthcare providers, because they help to prescribe your medication. You can accomplish this by distributing educational materials about your drug, attending medical conferences, and delivering free samples of your drug.

ACTIVE CAMPAIGNING

- Finally, It is important to campaign for the drug by using traditional advertising options such as television, radio, print or by new age advertising options such as digital platforms and social media. Moreover, Social media is a powerful tool that can be used to reach a large audience with your marketing message. You can use social media to share information about your drug, connect with potential patients, and build relationships with healthcare providers.

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THANK YOU

REGARDS,

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