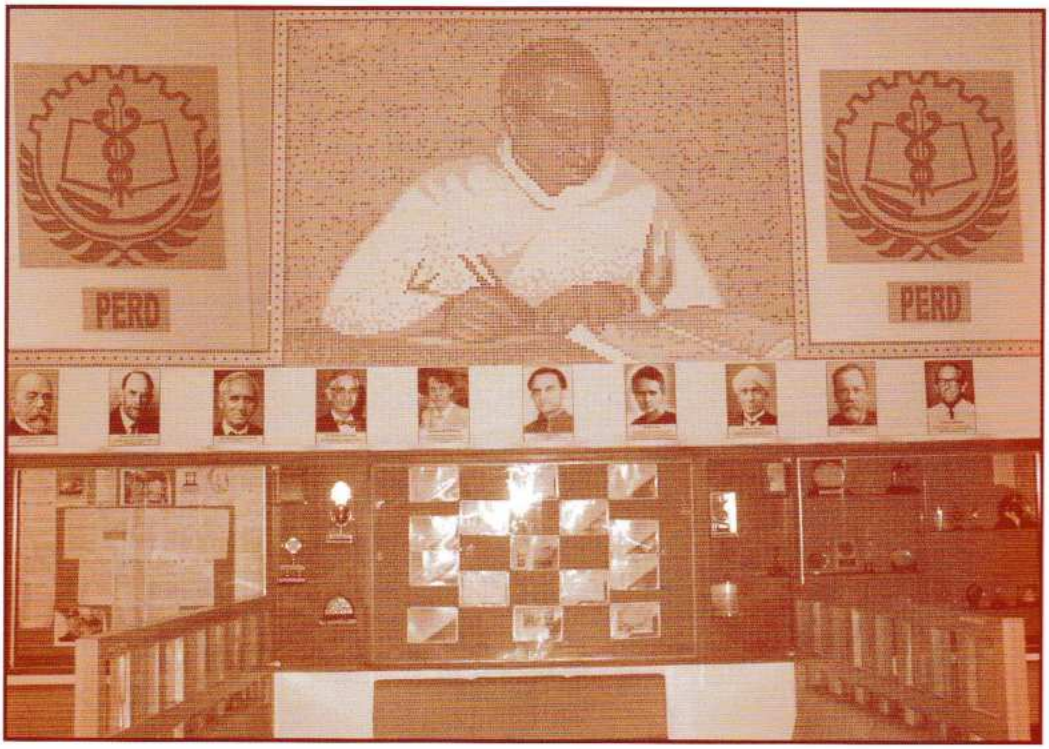
ESSAY COMPETITION-2018

SHRI B. V. PATEL EDUCATION TRUST
AHMEDABAD, GUJARAT



Shri Bhupendra V. Patel
2-8-1914 7-6-1974

As a visionary and an educationist acclaimed as the father of Drugs Legislation in India, Shri Bhupendra V. Patel made everlasting contributions to the field of pharmacy at national and international level. He was the first Director of the Drugs Control Administration of Gujarat State. He served as the Vice President of the Commonwealth Pharmaceutical Association. Shri B. V. Patel's life and career continue to be a source of inspiration to the pharmacy fraternity.

SHRI B. V. PATEL EDUCATION TRUST

(TRUST REG. NO. E-2571)

AHMEDABAD, GUJARAT

ESSAY COMPETITION-2018

ON

"ADVERTISING IN PHARMACEUTICALS: THERAPEUTIC OR TOXIC"

ESSAY COMPETITION - 2018

Subject

"ADVERTISING IN PHARMACEUTICALS: THERAPEUTIC OR TOXIC"

Number of Entries
12 from all over India

PANEL OF JUDGES

Shri.Padmin Buch
Senior Faculty & In Charge
New Projects & IPR Entrepreneurship
Development Institute of India (EDII),
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Bhat Village, Gandhinagar (Dist.), Ahmedabad–382 428

Shri. Alap Adeshara
Director
Relox Diagnostics Private Ltd.
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B/H Divya Bhaskar,
S.G. Highway, Ahmedabad–380 051

Dr. Amita Joshi
Scientist-B
B.V. Patel PERD Centre
Near Sola Bridge,
Sarkhej–Gandhinagar Highway,
Thaltej, Ahmedabad–380 054

WINNERS

GOLD MEDAL
Dr. Vividha Sagar Pawar
M. Pharm, Ph.D.
Associate Professor
Bharati Vidyapeeth University, Poona College of Pharmacy,
Erandwane, Paud Road, Pune-411 038 (Maharashtra)

SILVER MEDAL
Dr. Prachi Pandey
M. Pharm, Ph.D.
Assistant Professor of Pharmaceutics
Babaria Institute of Pharmacy, BITS Edu. Campus,
Varnama, Vadodara-391 240 (Gujarat).

FIRST PRIZE GOLD MEDAL) - 2018

Dr. Vividha Sagar Pawar

Dr. Vividha Pawar is Associate Professor at Bharati Vidyapeeth University, Poona College of Pharmacy, Pune. She pursued her doctoral, post-graduation and graduation in pharmacy from Bharati Vidyapeeth University, Poona College of Pharmacy with distinction and Gold Medals. Dr. Vividha has received various research projects from UGC, University of Pune, DIAT (Pune), industrial and hospital collaborations; travel grants from Bharati Vidyapeeth University as well as fellowships from AICTE, Dhirubhai Ambani Foundation, Ratan Tata Scholarship. Dr. Vividha has 24 publications in peer-reviewed international journals, one Indian patent, four book chapters in International books by Elsevier and CRC Press and has authored a book in Pharmaceutical Microbiology. She has been felicitated with Best Scientific Awards at International Conferences organized by National Universities of Thailand and Sri Lanka. She has been awarded at Indian Pharmaceutical Congress (IPC) and various symposiums by APTI, ICT, IIT and IPA for her research work. Dr. Vividha was a prestigious member of parliament (MP) for special youth parliamentary sessions organized by UNAIDS and Government of India. She is life member of APTI, ISCA, IPGA, MSPC and reviewer to various journals. Also, she has topped the state board examinations during her secondary and higher secondary studies.

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SECOND PRIZE (SILVER MEDAL) - 2018

Dr. Prachi Pandey

Dr. Prachi Pandey is currently working as Assistant Professor of Pharmaceutics at Babaria Institute of Pharmacy, Vadodara. She has done M.Pharm from Birla Institute of Technology and Ph.D in Pharmacy from GTU, Ahmedabad. She has also completed her PG Diploma in Patent Laws from NALSAR University, Hyderabad with 1st rank in India. Dr. Prachi has worked on nanocarriers based formulations such as liposomes, transferosomes, niosomes, microsponges etc. as transdermal drug delivery system. She has evaluated and established Proof-of-concept (POC) for the controlled release formulations and exercised quality by design (QBD) concept using statistical softwares for screening of quality attributes of process and composition for formulation development.

Dr. Prachi has received a research grant of Rs 14,50,000/- under Research Promotion Scheme of AICTE, New Delhi for her PhD work. Based on the outcomes of her research, she was shortlisted among top innovators & entrepreneurs of India in Year, 2015 through the event organized by AICTE,DST- Govt. of India & CII held at IIT, Delhi. She has also received "Innovate to Impact award" from GTU Innovation council for outstanding research work from the Vice Chancellor-GTU in year 2016.Her research projects were appreciated and selected as a potential startup for support by a panel of experts and entrepreneurs from different facets such as healthcare, law, finance, marketing etc at World's longest and biggest Sayaji Startup Summit, Vadodara in two consecutive years, 2017 and 2018.

Dr. Prachi has filed six patents in Indian patent office. She has also published eight research papers in national and International journals of repute. She has bagged the award for best paper published in Indian Journal of Pharmaceutical Education and Research for her paper on "Micro-computerized identification of crude drugs and development of standards through programming language Oracle 8i." Earlier, she was selected for paper presentation at Bhabha Atomic Research Centre, Anushaktinagar, Department of Atomic Energy, Trombay, Mumbai on the subject of "Benefits of radioactivity for serving humanity". In the National Essay contest of National Literacy Mission organized by Ministry of Human resources and development, New Delhi, she has Secured 2nd position in India. Dr. Prachi Pandey is also a recipient of Gold medal in 66th Indian Pharmaceutical congress, Hyderabad for 1st position in Essay contest organized by PERD Centre on 25th January, 2015.

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FIRST PRIZE (GOLD MEDAL) - 2018

"Advertising in Pharmaceuticals: Therapeutic or Toxic"

SYNOPSIS

- The pharmaceutical industry's primary aim is to maximize the profit to sell more of their products either by attempts to generate more prescriptions from physicians or direct to consumer advertising of its products through media.
- Pharmaceutical company's expenditure on advertising and marketing far exceeds that of its research budget.
- Advertising strategies including pharmaceutical sales representative detailing to physicians and pharmacists, direct to user advertising, sponsoring journal publications and advertisements can negatively influence both, patients and the health care professionals.
- Health care professionals and patients are increasing their reliance on the Internet as a source of health and medical information, prompting pharmaceutical companies to look at digital channels for opportunities to reach their target audiences.
- There is a need for the government to intervene and curb the advertisements with misleading and fake claims.

- Hours spent by physicians in industry-supported continuing medical education (CME) is greater than that from any professional set up. Such information must be made mandatory for disclosure to the general public, pharmacists and drug manufacturers.
- Establishment of a powerful regulatory authority and framing of strong legislation at national level along with adoption of ethical practices globally is required to address above challenges.
- Existing acts viz. The Drugs and Magic Remedies (Objectionable Advertisements) Act 1954 and The Drugs and Cosmetics Rules, 1945 should be amended.
- Advertising of generic and economic alternatives, awareness of critical ailment treatments or vaccines and improvement in patient comprehension would help to devise an apt pharmaceutical advertising strategy with special emphasis on the role of regulatory agencies in it and stringent measures undertaken to balance the benefits as against risks of drug advertised.


Be Wise!
Get your child fully immunized
Rx
ADVERTISING IN PHARMACEUTICALS: THERAPEUTIC OR TOXIC
SAVE
₹₹₹
INSTANT RESULTS!
PILLS
BUY NOW
Medicines
Branded
Generic
ONLINE

"Advertising in Pharmaceuticals: Therapeutic or Toxic"

INTRODUCTION:

'Do boond zindagi ki' echoes in every Indian's head in India's biggest superstar baritone. This helped in eradicating polio from India..... And then our government roped in Amitabh Bachchan as the face of the national campaign against Tuberculosis (TB) with ***'TB harega, desh jitega'.*** Similar advertisements in pharmaceutical and healthcare sector are useful in creating mass awareness and response for prophylaxis and treatment of diverse ailments. **With good comes bad.....** Few years back, Haridwar court penalized Baba Ramdev's Patanjali Ayurved with a fine of 11 lakh rupees for the misleading and misbranding advertisements' related to five products. One such product was Patanjali Dant Kanti claimed earlier to treat swollen and bleeding of gums, yellowing of teeth and pyorrhoea. Advertising Standards Council of India (ASCI) discovered 25 Patanjali Ayurved advertisements on hoardings, newspaper, radio, TV, print and social media to be misleading without scientific data to prove their claims.

This story doesn't confines only to developing nations like India but it has become the global saga. Fineyog.com website offers overseas sell of Patanjali products such as *Divya Yauvanamrit Vati* for treating impotence in men, medicine for hearing loss as well as one that treats

infertility in women. However, these violate the ASCI guidelines and the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954. The 2014 settlement case banned L'Oréal, USA for making false anti-aging claims devoid of scientific evidence. Every future violation by L'Oreal would cost it $16,000 fine. Until 2009, Allergan marketed the eyelash thickening drug, Latisse with a marketing blitz featuring actress Brooke Shields, flaunting her longer, thicker lashes from the drug. Nonetheless the company website scarcely cited about mentioned Latisse's offensive side effects such as permanent darkening of eye color, microbial infections leading to blindness and hair growth beyond the treatment area. In September 2009, the United States Food and Drug Administration (USFDA) warned Allergan for its misleading claims about Latisse and demanded the company to fix the Website immediately.

Advertisements (ads) are compelling strategies that affects the consumer by either making him aware or hypnotize. They consume a significant expenditure of any pharmaceutical company to elevate the sales via marketing. Basically, advertisements are paid-for communication, addressed to the health care professionals or public, the purpose of which is to influence the attitudes and preferences of the end user. However, it is essential to weigh the benefits *vs.* risks of the pharmaceutical advertisements in the interests of patients. Pharmaceutical set ups promote drugs and cosmetic products to healthcare providers like physicians and pharmacists as well as the patients, the end user of product for

marketing to increase their revenue. Based on the type and intended application of a formulation, there are different types of ads as shown in **Figure-1.**

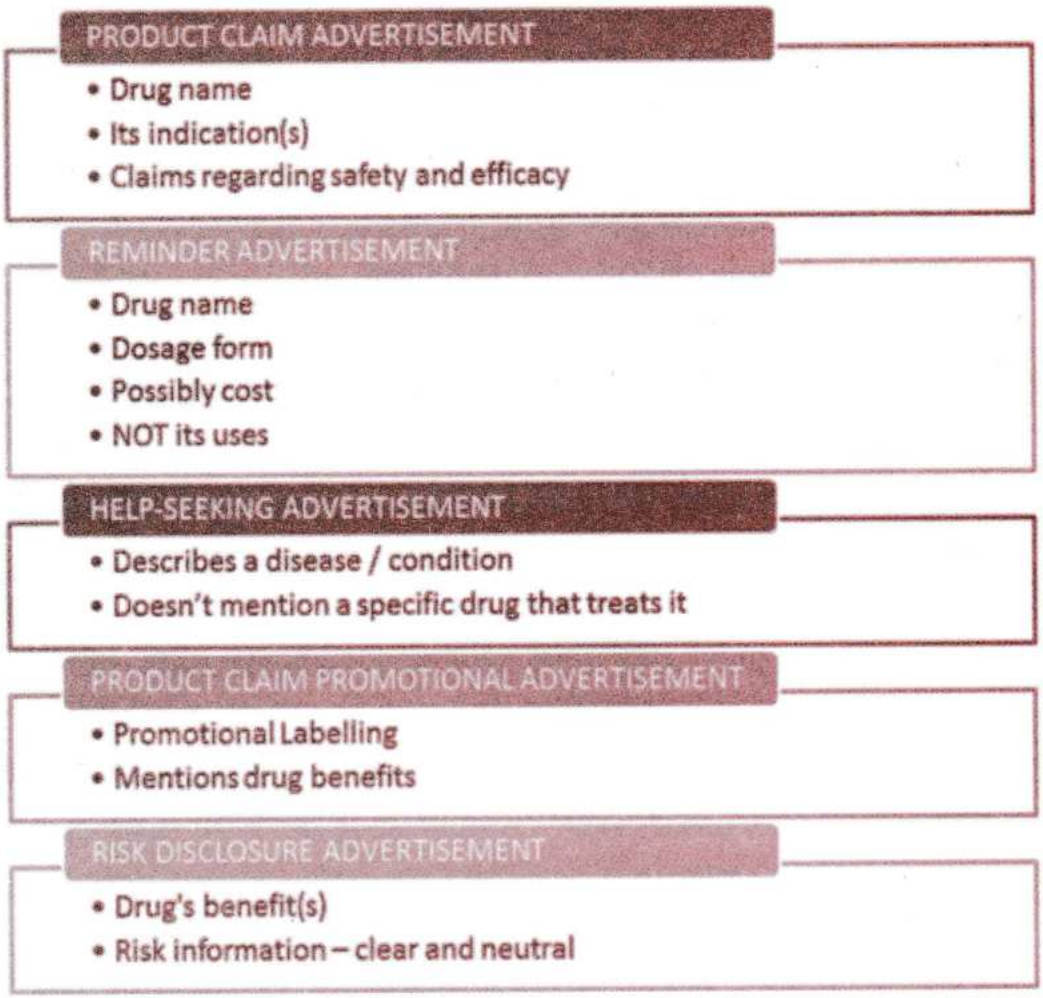

Figure-1: Types of Drug Advertisements

ADVERTISING TO HEALTHCARE PROVIDERS:

Trust is considered to be a cornerstone of health care provider-patient relationship. Hence, conventional pharmaceutical promotional activities embrace pharmaceutical sales representative's detailing to physicians, free sample distribution, detailing to hospitals, sponsoring continuing medical education (CME). Unlike other business and trade practices, medical ethics is an imperative part of health care for inculcating professionalism and building trust. However, it is well known that the nexus between pharma sales representatives and health care providers have respective conflict of interests for financial benefits.

Drugs as modern therapeutics have become expensive and pharmaceutical companies stand to gain a lot if more of their brand drugs are sold. Pharmaceutical industry need to persuade physicians, the prescribers to recommend their brand products preferentially and in high volumes via one-on-one marketing in the form of physician-pharmaceutical sales representative (PSR) interactions, also called as detailing. In detailing, PSRs convince the physicians about the benefits of their brand and the need to prescribe them. Marketing may not be the sole objective or purpose of detailing; it may aid in updating the physicians, community, clinical, wholesale and retail pharmacists about the pros and cons of using their formulations and to keep them abreast with the cutting-edge developments in drug delivery science.

However, there exists a thin borderline between candid recommendation and lucrative persuasion. Smart marketing strategies and tactics of PSRs on behalf of the companies like offering gifts, friendship and flattery can influence the physicians and practicing pharmacists to prescribe and dispense their brand drugs in excess. Doctor dinner diplomacies are an effective way for physicians to acquire educational information from respected peers. These meetings are sponsored by some pharmaceutical companies. Also, public and private insurers prompt the writing of prescriptions by physicians to restrict the number and types of drugs that the insurer will cover. Authentic prescriptions are necessary to help patients; the profit incentives create an opportunity for misuse and conflict of interest leading to violation of medical ethics on the part of the health care providers.

DIRECT-TO-CONSUMER (DTC) ADVERTISING:

DTC is an effort made by pharmaceutical companies to promote their products directly to patients by exploring popular media such as radio, television, newspapers, magazines, hoardings and social media. Much of the DTC advertising budgets are diverted from traditional (television, newspaper, magazine, radio) media to digital promotion like product web sites, online display advertising, search engine marketing, social media campaigns and mobile app advertising.

In 2017, the US pharmaceutical industry paid out $6.1 billion on advertising prescription drugs directly to consumers. Post 1962, these ads have been regulated by USFDA to safeguard that they are not misleading. In India, there is dearth of regulations in context of DTC ads. No federal law has ever banned DTC advertising. Until the 1980s, pharmaceutical companies gave information about prescription drugs only to physicians and pharmacists. Since 1980s, few drug companies started offering general public more direct access to this information through DTC ads.

Advocates of DTC ads assert the informative nature of ads as they inform patients about ailments and possible remedies, encourage people to seek medical assistance, help remove stigma associated with medical conditions and arrange for vital sales revenue to fund costly research and development (R&D) of new drugs. Antagonists argue that DTC ads mislead patients, promote drugs before long-term safety-profiles are established, medicalize and stigmatize normal conditions and bodily functions like wrinkles and low testosterone, waste valuable medical appointment time, responsible for multiple resistance and have led to overuse and hence, dependency of prescription drugs.

OFF-LABEL PROMOTION AND SELF-REGULATION OF PHARMACEUTICAL PRODUCTS

This defines the promotional role via published articles in peer reviewed journals and technical documentation by health

organizations like World Health Organization (WHO), private-social associations and NGOs working in the health care sector. Non-profit organization of pharmaceutical producers of India (OPPI) have illustrated the misleading information in pharmaceutical advertisements, technical document and articles published in scientific journals.

Morally, this helps to drive research notions into practical therapeutic tools by translating the novelty into the effective therapeutic measure. Recent legal cases and judgments have proved instrumental in providing access to pharmaceutical industry documents revealing new marketing strategies for drugs. Activities once considered independent of promotional intent, comprising CME and medical research are used. These days, many organizations are sponsoring and offering financial grants for promoting research and publish related data in peer reviewed journals. Such articles are influential in drug promotion for the medical literature; even it may lead to alleged suppression of unfavorable study results. Still ethical aspects of this practice continue to be a matter of debate. These publications and technological reports might be manipulated to influence the physicians prescribing and pharmacists dispensing practices. This may be harmful to the patients along with levying a financial burden. Publishing the pharmaceutical findings in scientific journals has also been debated as it is suspected to manipulate the findings to endorse certain drug formulations.

FRAMING AN 'IDEAL PHARMACEUTICAL ADVERTISING STRATEGY': Amendments, Abolitions and Embellishments

Legalizing DTC advertising

- Currently, United States and New Zealand are the only two countries to legalize the direct-to-consumer (DTC) advertising of prescription drugs. In India, there is need to encourage the establishment of a regulatory body as a watchdog over DTC advertisements.
- It is very apparent the existing Acts and Regulations doesn't allow to share information pertaining to a drug with a consumer/patient directly by manufacturers/importers in order to prohibit self-medication.
- So, the existing Acts must be amended in a manner to include activities, which educates the patients about drugs, it will foster them to understand the treatment procedure performed by the medical practitioners leading to patient compliance of the drugs prescribed along with removing social stigma associated with certain diseases.

Leave no stone unturned

- Regulations and ethical guidelines must be made to address every type of advertisement as mentioned in **figure-1.** Even USFDA have regulatory guidelines for few advertisements.
- As per the FDA regulatory requirements, product claim ads are made with a fair balance and risks are required to be

included in a brief summary if it is for broadcast ads only. Risks must be included in 'major statement' and 'adequate provision' for access to a 'brief summary' is essential.

- For reminder ads, fair balance doesn't apply as no product claims are made. Here, there is no need of mentioning risks. Nonetheless, FDA limit such ads for drugs with serious risks (boxed warning).
- In help seeking ads, there is absence of product reference; fair balance and inclusion of risks is not required.
- Similar type of framework must be legalized in India.
- With growth of digital and social media, all developing and developed nations needs to address other types of ads.
- In product claim promotion advertisements, use of a drug is endorsed via 'promotional labeling' that includes brochures, materials mailed to consumers, and other types of materials distributed by drug companies. If these materials mention the drug's benefits, they must also include the drug's prescribing information.
- Risk disclosure advertisements must exhibit the drug benefits with detailed information on the associated risk; these pertain more to critical formulations and molecules with narrow therapeutic window.
- While framing similar legal structure for India pharmaceutical advertisements, we need to cover all possible type of ads so that there is no legal escape for pharma giants and safety to patients is ensured.

Restrain product specific ads

- Advertisement may instill product preferences in consumers by providing information, training or incentives to compare benefits, risks, and economy of available treatment alternatives.
- It has been proposed that DTC advertisements be replaced with non-branded informational campaigns with comparable educational benefits that would be safer, more effective and better economical option.
- Drug manufacturers can divert the same allotted budget for marketing to sponsor an informational advertisement that lists the benefits of a drug class and encourages patients to discuss with their physicians the treatment choices and cross-pathy.
- Moreover, a tax system can be used to generate subsidies for public and private mass media campaigns aimed at awareness about common and critical medical conditions in addition to the evidence-based therapies with their health care providers.

Addressing the conflict of interest issues and promote moral and medical ethics

- In context of India, physicians accepting freebies like gifts and foreign jaunts from pharmaceutical companies will be punished as per the Medical Council of India (MCI) notified ethical guidelines under the Indian Medical Council

(Professional Conduct, Etiquette and Ethics) (Amendment) Regulations, 2015.

- The range of punishment will range from a censure for gifts of up to Rs.5000 to deletion of the errant doctor's name from the state or national medical register for a period of one year or more for perks valued more than Rs.1 lakh.
- Such guidelines would allow the medical practitioners to carry out research work funded by pharma companies with the assurance that the research proposals are transparent, have all the essential sanctions, it fulfills the legal obligations, the funding is disclosed along with proper care and facilities provided to the volunteers.
- Any contravention for the first time will merit a censure; a second offence would mean deletion of his/her name from the medical register.
- Such stringent regulations and punishments are essential to assure safe drug use.
- Any physician or pharmacist should not ethically endorse any medical product unless the results of an efficacy or other study done is established or reported in an appropriate scientific body or journal.

Curbing superlative claims

- Health care providers, DTC and Off-label advertising states many superlative claims without any further scientific evidence.

- Most of the claims question on the safety and efficacy of drugs.
- Commonly claimed terms are high-quality, outstanding, 100% guaranteed, no side effects, money back guarantee, unsurpassed, unmatched, fastest, best, superior, safest, trusted, first line, powerful and so on.
- Advertisements are usually placed strategically in the appropriate therapeutic sections to alter the claims based on violations as presented in **figure-2.** These generalized claims must not go unattended in the interest of patient safety.

Ads related to Cosmetics, Ayurveda, Homeopathy, Siddha and Unani medicines

- In India, DTC ads of prescription allopathic drugs (Schedule H and Schedule X) are not allowed.
- Cosmetics and AYUSH formulations that is Ayurveda, Unani, Siddha and Homeopathy are allowed for public advertising to consumers directly as long as they do not infringe the Drugs and Magic Remedies Act, 1954.
- The Drug and Magic Remedies (Objectionable Advertisement) Act and Rules 1954 enlists critical ailments for which no advertising is permitted along with prohibition of false, misleading and wrong claims. There is a growing need to clearly define the accuracy and educational content of the advertisements and have legislation on consequences for defaulting companies and products with false claims or going awry from the Acts and Regulations.

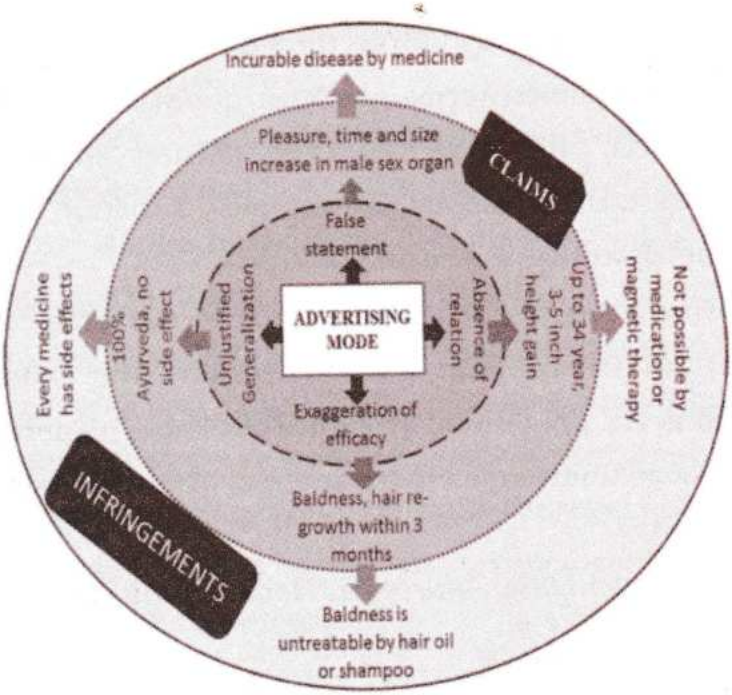

Figure-2: Common drug promotional claims and their violations

Allied Measures

- Drug companies could mention in their advertisements if a generic version is available so as to reach the masses who cannot afford expensive branded drugs.
- Regulatory bodies must **institute a mandatory waiting period** and delay its advertising for new drug to establish safety-adverse effect-clinical profile.
- Inclusion of statistically significant, specific **quantitative information** about potential benefits and risks of advertised drugs instead of the current qualitative and often emotionally driven messages must be made mandatory.

- Pharmaceutical companies must conduct **consumer pre-tests** to demonstrate to the regulatory bodies that the ads comply with the acts and regulations and confirm that all possible flagged issues have been addressed before an ad is aired to the public.
- Health centers with computers should include user-friendly interfaces, touch screens, voice recognition devices and hand-held remote controls to reach patients who lack computer skills or have low literacy levels and improve **patient comprehension.**
- There is utmost need to establish regulations for **Online Advertising** with mandatory public notification when online content is sponsored by a pharmaceutical company. Drug manufacturers can use the Internet to collect adverse-event reports from consumers.
- It is essential to convert the voluntary **Uniform Code of Pharmaceutical Marketing Practices (UCPMP) 2015** into a mandatory code.

CONCLUSIONS AND FUTURE PRESPECTIVES:

With increase in the number of cases wherein pharmaceutical advertising practices are negatively affecting both, patients and the health care professionals, there is need to establish an independent regulatory body, adopt new regulations and amend the existing policies. Pharmaceutical companies are now exploring the emerging digital and e-promotional activities. So, it's time to evaluate the pros and cons of the pharmaceutical advertising strategies. Devising

public-funded academic detailing programs to replace industry-driven detailing can address the conflict of interest issues between pharmaceutical sales representative and the health care professionals. Government can take initiative in creating awareness about drugs and vaccines with proven clinical data during various campaigns. Thus, there is a pressing need for an optimum pharmaceutical advertising strategy with special emphasis on the role of regulatory agencies in it and stringent measures undertaken to maximize the benefits as against minimum the risks of consumer drug advertised.

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SECOND PRIZE (SILVER MEDAL) - 2018

"Advertising in Pharmaceuticals: Therapeutic or Toxic"

SYNOPSIS

Pharmaceutical industry in India has evolved over the years to become a world class industry. Research in areas of pharmacy, therapeutics and biomedical technology has seen a revolution in the last three decades. It has brought out innovative molecules for the betterment of mankind. For ensuring a steady demand and supply of these products to physicians, pharmaceutical manufacturers have traditionally deployed a large number of sales forces. In today's world, advertising is a powerful force that plays a significant role in shaping the attitude and behavior of people. As advertisements increases the sales of the drug, pharmaceutical companies are focusing and spending a lot in pharmaceutical drug advertising.

The influence of advertisements on choice of consumers is indisputable. This makes it imperative that advertisements must be fair and truthful. Inappropriate and incorrect advertising mislead consumers and violates their right to correct information that protects them against unsafe products and unfair services. The unwanted competition in the form of false advertisements can

hamper consumer decision. Drug advertising has become a platform in India in recent years to promote false drug claims and exaggerate drug efficacy using movie stars as spokesperson. Policies for ethical promotion of drugs are established at both national and international level. To control the drug advertisement practices for the safety of consumer, there are many laws existent for consumer protection against unfair trade practices. To control the drug advertisement practices for the safety of consumer, there are many laws existent for consumer protection against unfair trade practices.

The need of hour is that all the stakeholders in the pharmaceutical industries, regulatory bodies, Physicians and patients must work together to set benchmarks and standards for a more therapeutic and least toxic drug advertising. In order to achieve the aim of rational drug advertising, genuine information must be provided by filtering out all misleading and lucrative words and the prerequisite here is honesty and integrity in all stakeholders. It is mandatory to maintain a fair balance between promotion and ethics to make the pharmaceutical advertising more therapeutic and least toxic.

"Advertising in Pharmaceuticals: Therapeutic or Toxic"

INTRODUCTION :

Pharmaceutical industry in India has evolved over the past few years to emerge as world class industry. Research in areas of pharmacy, therapeutics and biomedical technology has seen a revolution in the last three decades. It has brought out innovative molecules for the betterment of mankind. For ensuring a steady demand and supply of these products to physicians, pharmaceutical manufacturers have traditionally deployed a large number of sales forces. In today's world, advertising is a powerful force that plays a significant role in shaping the attitude and behavior of people. As advertisements increases the sales of the drug, pharmaceutical companies are focusing and spending a lot in pharmaceutical drug advertising.

Although pharmaceutical industry has big marketing players with their business spread across countries, pharmaceutical advertising is restricted and regulated by FDA. It needs regular monitoring by government agencies and organizations authorized to supervise the advertising of drugs for both over the counter and prescription drugs. Legislative bodies like FDA have the right to determine which pharmaceutical product should be promoted to prevent health related hazards. Because of the involvement of multiple stakeholders in this field, there is a need to maintain transparency

and regular exchange of information and ideas amongst the key stakeholders like Patients, Physicians, Manufacturing Company, Marketers and Key Opinion Leaders.

Today the consumers are more aware, more conscious, more confident and better educated and hence are interested in their own healthcare management. The abundance of material available from different sources of information helps consumers to do a better analysis. Ultimately the aim of drug promotion is to earn profits and if the consumers understand the drug features and can utilize it well, then they are directly shifted from information seeking stage to action stage. Advertisers of prescription drugs make it possible by direct involvement of consumers in selecting the right drugs for them. Although in the process of drug marketing the fair balance between promotion and ethics must be taken in account. A very important aspect of genuine and reasonable pharmaceutical marketing advertising for a particular drug is to find out the stage where people are in the purchase behavior i.e Unaware, Aware or Interested.

The influence of advertisements on choice of consumers is indisputable. This makes it imperative that advertisements must be fair and truthful. Inappropriate and incorrect advertising mislead consumers and violates their right to correct information that protects them against unsafe products and unfair services. The unwanted competition in the form of false advertisements can

hamper consumer decision. Drug advertising has become a platform in India in recent years to promote false drug claims and to exaggerate drug efficacy using movie stars as spokesperson. False advertising affects consumer health. However, when the claims made by the manufacturer are false and detrimental to the consumers, the product advertisement becomes illegal. There are two categories of false and misleading advertisements. The first type of advertisements have the potential to cause consumers financial loss and mental harm since these advertisements infringe upon consumer's right to procure the right information and to make an informed choice. The second type of advertisements is meant for marketing and promoting efficacy of questionable medications. These types of advertisements have a high potential to cause harm to consumer health. The unlawful drug advertisement and the lack of integrity in the drug advertising leads to loss of trust among consumers, therefore the pharmaceutical manufacturers, mass media, advertising agencies and drug distributors must focus on the healthy development of drug advertising in India.

REGULATIONS OVER ADVERTIZING IN PHARMACEUTICALS:

Policies for ethical promotion of drugs are established at both national and international level. At the international level, prescription and OTC drug advertisement policies named "Ethical criteria for medicinal drug promotion" are proposed by World Health Organization (WHO).

In India, principles of prescription drug advertising are regulated by the "Organization of Pharmaceutical Producers of India (OPPI)". According to the regulations, no drug may purport or claim to prevent or cure or may convey to the intending user thereof any idea that it may prevent or cure one or more of the diseases or ailments specified in Schedule J. Also, it is prohibited to advertise medications that are for conditions which are regulated under the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954.

The direct to consumer (DTC) advertizing was introduced mainly for marketing medications among primarily healthcare professionals and includes advertising via TV, radio and mass media. With the advent of technology, pharmaceutical companies are also relying on different means to market their products which include "direct-to-consumer advertising" (DTCA). Currently, the United States and New Zealand are the only countries that allow DTCA of prescription drugs. Most other countries including the European Union and UK do not allow this form of marketing. Countries such as India, Canada, and South Korea have prohibited DTCA, but they do allow DTC of some formulations or certain advertisements in specified format.

In India, Direct to user advertising (DTCA) of prescription allopathic drugs (Schedule H and Schedule X) are not allowed. DTCA of only Ayush formulations that is Ayurvedic, Unani, Siddha and Homeopathy are allowed for public advertising to consumers as

long as they do not infringe the Drugs and Magic Remedies Act, 1954.The Drug and Magic Remedies (Objectionable Advertisement) Act and Rules 1954 mentions a list of ailments for which no advertising is permitted. It also prohibits false or misleading advertisements that end up making wrong claims. Thus, there is a growing need to clearly define the accuracy and educational content of the advertisements and have legislation on consequences for defaulting companies and products with false claims or going awry from the Drug and Magic Remedies (Objectionable Advertisement) Act and Rules 1954.

Even though DTC is banned in India since 1956, some pharmaceutical companies advertise emergency contraceptive pills using punch lines such as "Abortion say accha hai pregnancy ko rokna" (stopping pregnancy is better than abortion) and "ab ham hain tension free" (now I am tension free). Such advertisements have generated controversy since the emergency contraceptive pill, also known as the morning after pill reduces progesterone secretion and further delays menses, prevents ovulation and pregnancy. Other side effects include clinical depression, respiratory disorders, bulimia, high blood pressure, an increased risk of ectopic pregnancy, gallbladder disease, anorexia, ovarian cyst enlargement, weight gain and death. Such side effects are often not highlighted by the Indian pharmaceutical companies in the media due to lack of regulations and couples use the morning after pill as a regular contraceptive, mainly out of lack of awareness.

Hence, to prevent the misuse or overuse of drugs that have side effects, a proposal is being considered by the Drug Controller General of India (DCGI) that stops DTC advertising and sale of such drugs over the counter and instead ensures that they are sold as prescription drugs instead.

The World Health Organization has also expressed concern on the appropriateness of DTCA and its impact on global health and made a unanimous recommendation to prohibit DTCA at the 30th Annual meeting of countries in 2007.

The debate on the benefits and negative impact of DTCA has been going on around the globe and India too has not been left behind in the debate of legalizing and easing the legislation or imposing a total ban on DTCA and studying the increasing impact these advertisements on consumers. DTCA of drugs is having a profound effect on patients, doctors and health care organizations. It is important to understand its impact on the patient behavior. Pharmaceutical advertising can influence drug consuming behavior and many physicians have negative views of these advertisement.

- **Pros and cons of advertising of Pharmaceuticals on patients:**

❖ **Therapeutic Aspects of advertising:**

- **INFORMS, EDUCATES, AND EMPOWERS PATIENTS:**

The Internet, including online advertisements, has become an increasingly popular source of medical information for consumers. In a survey of US in year 2005 conducted on more than 6,000 adults indicated that, although the physician was still the most trusted source of information, 48.6% of the subjects went online first and then consulted their physician, whereas only 10.9% talked to their physician first. Online DTCA or other pharmaceutical company sponsored Web sites can also be used to inform patients about safety measures, risks, health warnings and adverse reactions in an easily understandable manner.

In a study carried out in 300 respondents for a period of 6 months from September to February 2011, at a tertiary care rural hospital in India the following findings were observed in terms of recollection about drugs due to advertisements.

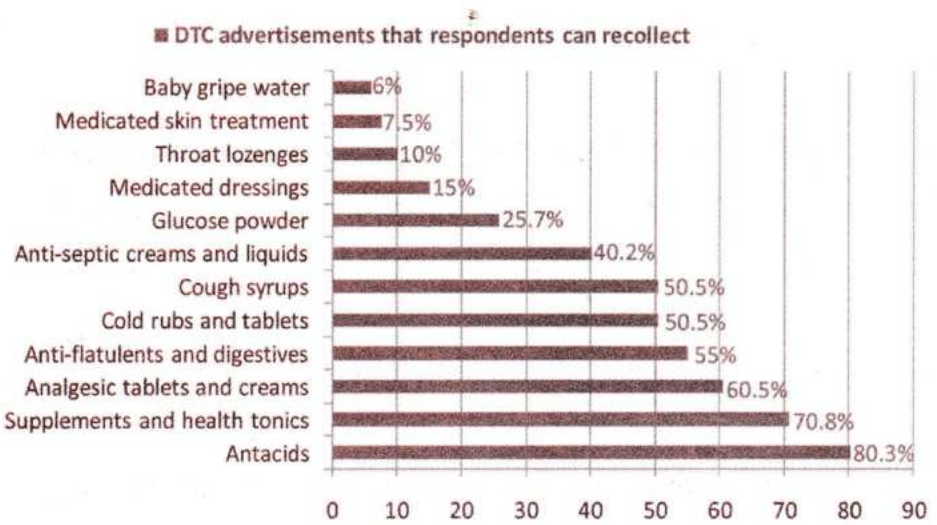


Figure-1:

Direct-to-consumer advertising that respondents can recollect

- Figure-1: depicts DTCA recollected by respondents. It was seen that advertisements featuring antacids, health tonics and supplements, analgesic tablets and creams, antiflatulents and digestives, cold rubs, and tablets as well as cough syrups had a high recall value (>50%).

- **ENCOURAGES PATIENTS TO CONTACT A CLINICIAN:**

  A common claim is that DTCA prompts patients to consult a health care provider to seek medical advice. A 2004 USFDA consumer survey found that exposure to DTCA prompted 27% of Americans to make an appointment with their doctor to talk about a condition they had not previously discussed. The effect of DTCA in increasing patient contact with health care

providers could also be beneficial by promoting dialogue about lifestyle changes that improve patients' health, whether or not a drug is prescribed.

- **PROMOTES PATIENT DIALOGUE WITH HEALTH CARE PROVIDERS :**

  Most health care professionals seem to agree that advertizing is beneficial because it promotes dialogue with patients. In the 2004 USFDA survey, 53% of physicians said DTCA led to better discussion with patients and 73% believed that consumer drug advertising helped patients ask more thoughtful questions.

- **ENCOURAGES PATIENT COMPLIANCE :**

  The data consistently show that small, but statistically significant, improvements in adherence occur among patients exposed to DTCA. This increased compliance is believed to be due to drug ads serving as a reminder about a patient's medical conditions and prescriptions. DTCA is also thought to reinforce physician recommendations and make patients more likely to follow treatment instructions.

The beneficial effect of DTCA on patient adherence has been detected in several research studies. In the 2004 FDA study, 33% of physicians reported that DTCA increased patient

adherence. In another study by Harvard University/ Massachusetts General Hospital and Harris Interactive, 46% of physicians said that they felt DTCA increased patient compliance.

In a study carried out in 300 respondents for a period of 6 months from September to February 2011, at a tertiary care rural hospital in India, the outcome of DTCA was found to be positive based on the survey as shown in the figure-2.

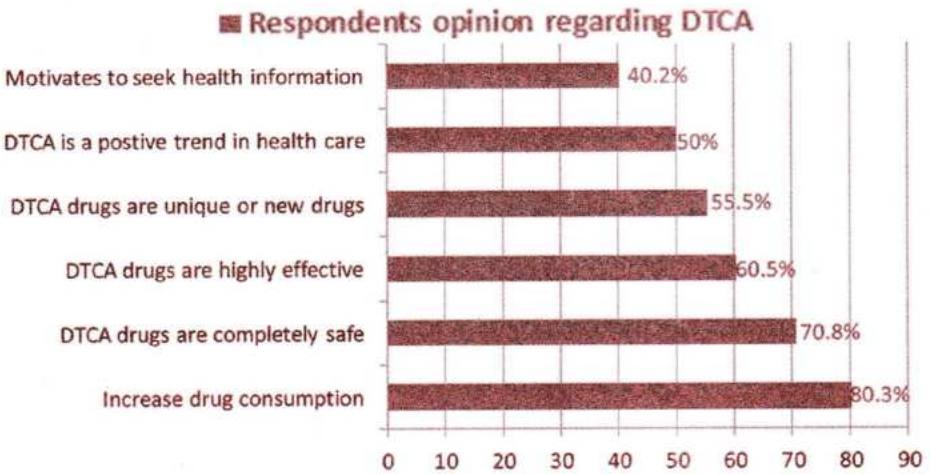


Figure-2:

Respondents opinion regarding direct-to-consumer advertising

The opinion of patients on DTCA was taken in the study. It was seen that patients were keen on buying the drugs after an exposure to DTCA. Their other opinions on DTCA were that the drugs marketed were completely safe, unique and highly

effective and this form of the advertisement is a positive trend in health care.

- **REDUCES UNDER-DIAGNOSIS AND UNDER-TREATMENT OF CONDITIONS:**

  Drug advertisements enhance patient perceptions about conditions that could be medically treatable and encourage them to consult with health care providers. In the 2004 FDA survey it was found that DTCA improved the diagnosis of illnesses, since 88% of patients who had inquired about a medication in response to a drug advertisement were suffering from such conditions that can be treated.

  Epoetin Alpha (Procrit, Ortho Biotech) provides an interesting example of how DTCA can have a positive impact on the diagnosis and treatment of a condition. Procrit is used to treat anemia by stimulating the production of hemoglobin-containing red blood cells, which can counteract fatigue. This drug was rarely prescribed before a DTC advertising campaign was conducted, because chemotherapy patients were not telling their doctors that they were fatigued. The advertisement for Procrit suggested that chemotherapy patients who were experiencing fatigue should discuss possible treatments with their physicians. This DTC advertising campaign spurred patient awareness and encouraged them to consult with their health care providers

about chemotherapy-associated fatigue. This led to a significant increase in the use of Procrit to treat anemic chemotherapy patients.

- **REMOVES THE STIGMA ASSOCIATED WITH CERTAIN DISEASES:**

  Consumer drug advertising for health problems that could be embarrassing to a patient, such as depression or erectile dysfunction (ED), can reduce the stigma associated with these conditions. For example, an advertising campaign for finasteride (Proscar, Merck), a treatment for benign prostatic hyperplasia, is widely regarded as having successfully raised awareness of a medical condition that men had been reluctant to discuss with their doctors.

- **ENCOURAGES PRODUCT COMPETITION AND LOWER PRICES:**

  Economic theory and evidences suggest that pharmaceutical prices are largely influenced by consumer, physician, and payer perceptions of product value. Advertisements of drugs to Consumers may lead to price increases because of demand, but the evidence also claim that drug advertisements stimulate increased competition, which leads to lower the prescription drug prices. Advertisements may also encourage early pharmacological management, resulting in cost-savings

from avoiding more expensive surgical interventions afterwards.

❖ **TOXIC ASPECTS :**

- **MISINFORMS PATIENTS:**

Although advertising may educate patients, but it also has the ability to misinform them. A common complaint is that advertising omits important information while spreading information. For example, in one study conducted in US, 74% of DTCA ads made some factual claims and rational arguments for use of the advertised drug, however, only 26% of the advertisements described risk factors or causes of the condition. Consumers have also been found to place unwarranted trust in DTC ads. One survey of consumers found that 45% of respondents thought that the ads were approved by the government, 38% thought that a medication had to be completely safe for it to be advertised and 17% thought that a drug known to have serious side effects could not be advertised.

Paradoxically, the inclusion of information about risks and adverse events in DTCA may also promote an unnecessary fear of side effects. The required risk warnings are so extreme that they cause consumers undue concern about drug safety and may cause noncompliance.

A study carried out in 300 respondents for a period of 6 months from September to February 2011, at a tertiary care rural hospital in India reveals the following mentioned statistics.

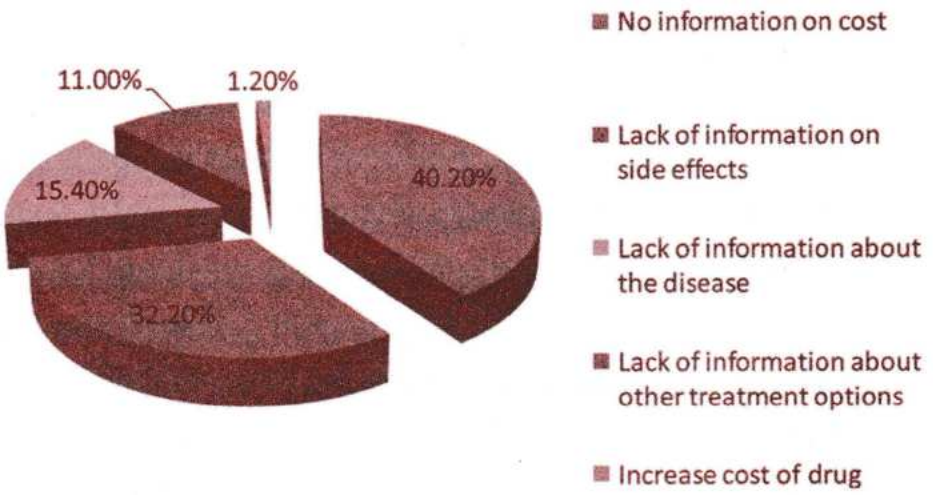


Figure-3:

Respondents dis-satisfaction with direct-to-consumer advertising

When asked for their opinion on what they thought were the negative effects of the DTCAs, a majority (70%) felt that the DTCA never mentioned the either the cost or side effects of the marketed product. The other issue which concerned a total of 26.4% of respondents was the lack of information of the disease and other treatment options. A few respondents also seemed to be concerned that the cost of the drug would increase if they were advertised.

- **OVEREMPHASIZES DRUG BENEFITS:**

  Advertizing for drugs may overemphasize potential benefits. In support of this view, content analytic studies have found that most DTC ads emphasize drug benefits over risks. A 2007 study in the *Journal of Health Communication* also found that the average DTC television commercial devotes more time to benefits than to risks. Disciplinary action by the FDA during 1997 to 2006 also confirmed that this has been a common problem. During this time period, nearly 84% of the regulatory letters for DTCA cited advertisements for either minimizing risks or omitting information about side effects or exaggerating a drug's effectiveness e.g., portraying the indication too broadly or making unsubstantiated claims of superiority over other drugs.

  Studies have found that when a claim presents a drug as being very efficacious, consumers do not make much effort to process the rest of the information within the message. Information about risks is also typically presented in often-ignored smaller prints which are not so legible. In addition, ads often show a mismatch between visual imagery and verbal messages when risk information is presented.

- **PROMOTION OF NEW DRUGS BEFORE SAFETY PROFILES ARE FULLY KNOWN:**

New drugs have been associated with previously unknown serious adverse events. This is particularly true for "first-in class" drugs. Clinical trials required for FDA approval are typically not designed to detect rare adverse effects, and current methods of postmarketing surveillance often fail to connect adverse events that have a high rate of background prevalence with the use of a particular drug. Drugs that are expected to be "blockbuster" sellers are also most heavily promoted early in the product's life cycle, which can present a public health risk because the drug's safety profile is not fully known at that point.

The safety problems with rofecoxib (Vioxx, Merck) are perhaps the most frequently cited example regarding this issue. Vioxx was among the most heavily promoted drugs in the U.S. from 1999 to 2004.During that time, Merck spent over $100 million per year to build the drug into a blockbuster seller, with annual sales of more than $1 billion in the U.S. Patients without knowing that it could lead to stroke or myocardial infarction. On September 30, 2004, Merck voluntarily withdrew Vioxx from the market.

Other drugs that were heavily promoted to consumers have also been linked to safety advisories, FDA black-box warnings, and withdrawals from the market. These include benoxaprofen (Oraflex, Eli Lilly) for arthritis, troglitazone (Rezulin, Parke-Davis) for diabetes, cisapride (Propulsid, Janssen) for gastric reflux, ceriva statin (Baycol, Bayer) for high cholesterol, and tegaserod (Zelnorm, Novartis) for irritable bowel syndrome in women.

- **MANUFACTURES DISEASE AND ENCOURAGES DRUG OVER-UTILIZATION:**

Advertizing may contribute to the "medicalization" of natural conditions, cosmetic issues, or trivial ailments, resulting in unnecessary overmedication. For this reason, advertizing may act as a threat to public health. One often cited example in literature is DTC ads for ED drugs, which seem to target men who may be experiencing normal variations in sexual performance. Studies show that only 10% of men experience a total inability to achieve an erection. Therefore, demand for ED drugs seem to be for occasional purpose, but under the influence of ads, men sometimes unnecessarily use the medication. Similarly, DTC drug ads have also been observed for redefining menopause as a hormone-deficiency disease rather than a normal midlife experience. This misleading information spread unhappiness and can cause severe

distress when a drug is unaffordable or when the response to a medication is disappointing.

- **INCREASES COSTS OF DRUGS:**

  Manufacturers often use advertizing to promote expensive drugs that might not offer any significant benefits over older and cheaper medications. For example, according to the conducted studies and survey, two heavily promoted diabetes treatments, rosiglitazone (Avandia, GlaxoSmithKline) and pioglitazone (Actos, Takeda), were found to be no more effective or safe than older drugs, even though they were much more expensive.

➢ **SUGGESTED CORRECTIVE MEASURES:**

The need of hour is that all the stakeholders in the pharmaceutical industries, regulatory bodies, Physicians and patients must work together to set benchmarks and standards for a more therapeutic and least toxic drug advertising. In order to achieve the aim of rational drug advertising, genuine information must be provided by filtering out all misleading and lucrative words and the prerequisite here is honesty and integrity in all stakeholders.

As per the regulatory guidelines and also by the nature of the Act, it is very apparent that there is no opportunity to share

the physician's work. (e.g. pens and notepads). The giving of a subsidy directly to a physician by a company's sales representative may create a relationship which could influence the use of the company's products, so it must be denied. Subsidies from industry should not be accepted for the costs of travel, lodging, or other personal expenses of physicians attending conferences or meetings.

Besides all this, the patient awareness is a vital factor to control the undesirable effects of the misleading information by using a thoughtful approach while selecting the right drugs for them along with consultation with their physician. On the other hand, the consumer must consider the positive aspects of receiving knowledge about drugs through information resources to keep them aware and updated.

➢ **CONCLUSION:**

In today's world, advertising is a powerful tool that plays a significant role in shaping the attitude and behavior of people. Pharmaceutical companies are nowadays focusing on pharmaceutical drug advertising to promote their products. Drug Advertising has definitely lots of significance in making the consumer aware and updated about new drugs and their uses. To control the drug advertisement practices for the safety of consumer, there are many laws existent for consumer

protection against unfair trade practices. Yet, false and misleading advertisements are still a threat to vulnerable consumers because of the poor enforcement of laws due to inability of the stakeholders to abide by the regulations. The need of the hour is to maintain a fair balance between promotion and ethics to make the pharmaceutical advertising more therapeutic and least toxic.

B. V. Patel Essay Competition History at a Glance

The trust conducts an all India level Essay Competition every year as one of its activities. The selection of the subject depends on the importance and the current happenings in the Sector. Any one interested in drugs and pharmaceuticals, academically, industrially or otherwise, can participate in the competition. The entries are generally invited in the month of July/August. The essays are evaluated independently by a panel of judges comprising of the expert luminaries of industry and academy. The essays of the winners are printed and distributed during the IPC since 1977.

The year-wise subjects chosen for the Essay Competition :

Year		Subject
1977	-	Good Manufacturing Practice in Parenterals
1978	-	Indian Pharmacopoeia for the Future
1979	-	Documentation and Record Keeping in Drug Manufacture
1980	-	Drug Distribution
1981	-	Review and Modification of Drugs Legislation in India
1982	-	Industry Oriented Pharmacy Education - Its Means and Modifications
1983	-	Role of Testing Laboratories in Assurance of Quality Drugs
1984	-	Material Management in Pharmaceutical Industry
1985	-	Status & Prospect Of Research and Development
1986	-	Manufacture of Dosage Forms - Problems and Remedies
1987	-	Advances in the Technology of Industrial Pharmacy
1988	-	Role of Combination Products in Drug Therapy
1989	-	1. Continuing Education in Pharmacy
		2. Trends in Pharmaceutical Research

1990	-	Restructuring of Pharmacy Education
1991	-	Biotechnology in Pharmacy
1992	-	Role of Pharmacists on Stability of Pharmaceuticals
1993	-	ISO 9000 and its Applicability to Pharmaceuticals-A Pharmacists Perception
1994	-	Challenges and Opportunities in Pharmaceutical Research
1995	-	New Drug Delivery Systems - Indian Scenario
1996	-	Traditional Medicines - Sources of New Drugs
1997	-	Clinical Pharmacy in India - Emerging Facet of the Pharmacy Profession
1998	-	Community Pharmacy
1999	-	Revision of Indian Patents Act 1970 And its Impact on Availability and Cost of New Pharamceuticals
2000	-	Information Technology-Revolutionary Impact on Pharmaceutical, Sciences
2001	-	Aesthetic Design of A Manufacturing Unit in Compliance with National Regulatory Requriement and WHO - GMP
2002	-	Genomics and Proteomics: Treasure for Drug Discovery
2003	-	Pharmacy Education: Current Problems and Suggested Solutions
2004	-	Industrial Growth in Changing Scenario: Strategic Options for Small and Medium Enterprises (SMES)
2005	-	Roadmap to Globalization of Ayurveda as Recognized Healthcare System
2006	-	Prospects for CRO in next Five Years: Indian Capabilities
2007	-	Distribution of Pharmaceuticals and Drugs in India: Its Science, Commerce and Ethics
2008	-	Medical Devices: Opportunities For Indian Industry

2009	-	Steps to Revitalize Pharmacy Profession in India
2010	-	Innovation: Driver for Growth of Indian Pharma ?
2011	-	Vaccines In Healthcare: Indian Perspective And Potential
2012	-	Drug Affordability in India - Post 2005
2013	-	Patent - The Need for Efficient Handling of Disputes
2014	-	Pharmacists in a State of Mortification: Reasons, Responsibilities of Stakeholders and Remedy
2015	-	Pathway for Zero Defect Product and Production in Pharmaceutical Industry
2016	-	Clinical Trials in India and China: Advantages and Disadvantages
2017	-	Stem Cell Based Therapeutics: A Revolution Changing the Treatment Paradigm

B.V. Patel Pharmaceutical Education & Research Development (PERD) Centre

.... in the spirit of progress

Services
- Formulation Development
- Toxicity Studies
- Cell Based Assays
- Impurity Profiling
- Custom Synthesis
- Herbal Drugs Standards
- Stability Studies

Education
- Ph. D Programme
- Dissertations (M. Sc., M. Pharm)
- Certificate Courses
- Continuing Education Programme
- Hands on Training

Training
- Mammalian Cell Culture
- PCR & qPCR
- Molecular Biology
- HPTLC & HPLC
- Genetic Engineering
- Molecular Marker
- Analytical Instrumentation

Industrial Services

Formulation and Analytical Method Development

- Development of novel dosage form, transdermal drug delivery and Iontophoretic system
- Preformulation studies and permeability assessment
- Cost-effective solutions for development of poorly soluble pharmaceutical ingredients
- Analytical method development and validation

Synthesis of APIs and NCEs

- Synthesis of compound libraries, APIs and drug metabolites
- Analytical method development and stress degradation studies of APIs and natural products
- 3D-QSAR and molecular docking facility
- Analysis of NCEs and purification

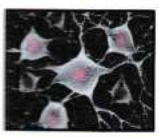
Pre-Clinical Studies

- Pharmacological studies
- Toxicity studies
- Pre-clinical pharmacokinetic studies
- In vitro cytotoxicity assay for various pharmaceutical drugs

Quality Control and Quality Assurance of Herbals

- Identification, authentication and standardization of herbal drugs and polyherbal formulations
- Analysis of steroids from herbal drugs
- Development of phytochemical profiles (fingerprint) of medicinal plants
- Bioassay guided isolation of active marker compounds

Microbiology



- Custom based pharmacogenomic testing for different genes and drug metabolizing enzymes
- Evaluation of anti-bacterial, anti-fungal, anti-mycobacterial activity
- Microbial load testing
- Development of tissue cultures of medicinally and economically important plants

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Development of skilled personnel in various field of pharmacy and allied sciences. Hands-on-training workshops, summer training and dissertation programs, tailor made hands-on-training program for analytical instruments like HPLC, HPTLC, IR, LC-MS, PCR, Real-time PCR etc.

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