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Dosing Decency: A Retrospective Analysis of Pharmaceutical Practices and Ethical Dilemmas

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Abstract

“Dosing Decency: A Retrospective Analysis of Pharmaceutical Practices and Ethical Dilemmas” a review delves into the intricate tapestry of the pharmaceutical industry's evolution, scrutinising its ethical compass across different epochs. This review meticulously examines the historical trajectory of drug development, marketing strategies, and regulatory frameworks, juxtaposing them against contemporary ethical standards and societal expectations. Through a critical lens, it assesses landmark case studies that have shaped public discourse and policy, elucidating the perennial tension between commercial imperatives and moral responsibility. The analysis further explores the role of key stakeholders, including regulatory bodies, healthcare professionals, and the public, in fostering a paradigm that balances innovation with integrity. By reflecting on past practices and their ethical ramifications, this review aims to inform future discourse on ethical pharmaceutical practices, advocating for a harmonised approach that prioritises patient welfare and societal trust. Ultimately, it aspires to contribute to the ongoing dialogue on ethical stewardship in the pharmaceutical realm, underscoring the necessity of principled conduct in advancing public health.

Key Words: Pharmaceutical Practice, Ethics, Evolution, Healthcare, Advancement

1. Introduction ^[1-8]

Pharmaceuticals are the cornerstone of modern healthcare, being central in alleviating suffering, prolonging life, and improving overall well-being. From antibiotics to vaccines, pharmaceuticals have revolutionized medical treatment, making once-fatal diseases manageable and significantly improving quality of life. However, the pharmaceutical industry is not without its ethical challenges. It underscores the relevance of pharmaceuticals in healthcare and society, stressing the ethical imperatives in pharmaceutical development and distribution, amid a historical context of key periods and themes shaping the industry.

A. Brief Overview of the Significance of Pharmaceuticals in Healthcare and Society

Pharmaceuticals have transformed healthcare by providing effective treatments for a myriad of diseases. Antibiotics, for instance, have saved countless lives by combating bacterial infections, while vaccines have eradicated or significantly reduced the prevalence of once-deadly diseases such as smallpox and polio. Furthermore, pharmaceuticals are essential in coping with enduring ailments like diabetes, hypertension, and HIV/AIDS, enabling patients to lead productive lives. To boot their therapeutic benefits, pharmaceuticals also contribute to economic growth and development. The pharmaceutical industry generates substantial revenue globally and fosters innovation through research and development. Moreover, pharmaceutical companies create job opportunities and drive scientific advancements, thus bolstering economies and improving standards of living. However, the widespread availability and use of pharmaceuticals raise ethical concerns, particularly regarding access, affordability, and safety. Disparities in access to essential medicines persist, with many individuals in low-income countries lacking access to life-saving treatments due to cost barriers. Furthermore, the pursuit of profit sometimes leads to unethical practices such as price gouging and the promotion of unnecessary or unsafe medications.

B. Importance of Ethics in Pharmaceutical Development and Distribution

Ethical considerations are paramount in every stage of pharmaceutical development and distribution, from drug discovery to post-marketing surveillance. The ethical principle of beneficence obligates pharmaceutical companies to prioritize the well-being of patients by developing safe and effective medications. Similarly, the principle of nonmaleficence prohibits the production and dissemination of medication that might result harm or have adverse effects outweighing their benefits. Moreover, pharmaceutical companies bear a moral obligation to guarantee fair access to vital medication, especially for marginalized communities. This entails balancing the need for profit with the obligation to provide affordable medications to those in need. Initiatives such as differential pricing and tiered pricing structures can help mitigate disparities in access and ensure that life-saving treatments are accessible to all. Transparency and integrity are also essential ethical considerations in pharmaceutical development and distribution. Companies must disclose accurate information about the safety and efficacy of their products, alongside possible conflicts of interest concerning research funding and marketing practices. Furthermore, regulatory agencies play a crucial role in upholding ethical standards by monitoring compliance with regulations and holding companies accountable for unethical behavior.

2. Ancient Origins of Pharmaceuticals ^[9-16]

The pursuit of alleviating human suffering through medicinal substances dates back to antiquity, where early civilizations tapped into nature's resources to discover remedies for various ailments. This embarks on a journey through time, exploring the ancient origins of pharmaceuticals. It delves into the intricate tapestry of early civilizations, such as the Egyptians, Greeks, and Chinese, to unravel their profound contributions to pharmaceutical knowledge. By examining historical texts, archaeological findings, and modern research, we gain insight into the ingenuity and wisdom of our ancestors in harnessing plants and natural elements for healing intentions.

A. Exploration of Early Civilizations' Harnessing of Flora and Natural Agents in Healing Practice

Pharmaceuticals find their origins in the ancient epochs of human civilization when ancient societies began experimenting with flora and natural substances to alleviate sickness and maladies. In ancient Mesopotamia, the Sumerians documented the therapeutic properties of various plants in clay tablets dating back to around 2600 BCE. These early records provide evidence of a sophisticated understanding of herbal medicine, with plants like

licorice, leveraging the medicinal qualities opium poppy and mandrake. Similarly, the ancient Egyptians left behind a rich legacy of medicinal knowledge, as evidenced by the Ebers Papyrus, one of the oldest preserved medical texts dating back to around 1550 BCE. This papyrus contains over 700 remedies, including treatments for gastrointestinal disorders, skin ailments, and infectious diseases. Ingredients such as garlic, frankincense, and juniper were commonly used in Egyptian medicine, embodying the civilization's profound affinity with nature. In ancient Greece, the father of Western medicine, Hippocrates, revolutionized the practice of medicine by emphasizing the relevance of scrutiny, diagnosis, and treatment. His synergistic approach to healthcare focused on the balance of bodily humors and intergrating herbs and diet to restore health. The works of Hippocrates and his followers laid the bedrock of Greek *materia medica*, a compendium of medicinal plants and their therapeutic uses.

B. Contributions of Ancient Cultures to Pharmaceutical Knowledge

Egyptian Medicine: The ancient Egyptians made significant contributions to pharmaceutical knowledge through their extensive use of medicinal plants and herbs. The Edwin Smith Papyrus, another ancient medical text dating back to around 1600 BCE, provides detailed instructions on surgical techniques and treatments for injuries. Substances like honey, aloe vera, and myrrh were commonly used in Egyptian medicine for their healing properties. Additionally, the process of mummification employed various natural preservatives and antibacterial agents, indicating a sophisticated understanding of pharmacology.

Greek Medicine: The Greeks inherited much of their medical knowledge from the Egyptians and Mesopotamians but expanded upon it through rigorous observation and experimentation. The works of Hippocrates, such as the Hippocratic Corpus, codified medical practices and laid the groundwork for rational medicine. Greek physicians like Dioscorides further advanced pharmaceutical knowledge with their comprehensive pharmacopoeias, such as "De Materia Medica," which cataloged hundreds of medicinal plants and their therapeutic uses.

Chinese Medicine: Ancient China boasts a rich tradition of herbal medicine that dates back over 2,000 years. The Huangdi Neijing, or Yellow Emperor's Inner Canon, is a foundational text of traditional Chinese medicine (TCM) that emphasizes the balance of qi (vital energy) intrinsically. Chinese pharmacology is centered around the notion of herbal formulas, which combine multiple medicinal herbs to target specific health conditions. Herbs such as ginseng, licorice, and ginger are fundamental to TCM and continue to be widely used in modern herbal medicine.

3. Medieval and Renaissance Period ^[17-21]

The medieval and Renaissance periods mark significant epochs in human history, characterized by profound intellectual, cultural, and scientific transformations. Within the vast tapestry of advancements, the evolution of pharmacy stands as a testament to mankind's enduring quest for understanding and harnessing the power of nature for healing. This review delves into three pivotal aspects of pharmacy during these eras: the development of apothecaries and early pharmacopoeias, the influence of alchemy on the pursuit of the philosopher's stone and elixir of life, and the emergence of early forms of pharmaceutical regulation and quality control.

A. Development of Apothecaries and Early Pharmacopoeias

During the medieval period, the practice of pharmacy was intimately intertwined in the practice of herbalism and folk medicine. Apothecaries, often operating as a segment of monastic infirmaries or as independent practitioners, was pivotal in preparing and dispensing remedies derived from botanical sources. The lore of medicinal plants was shared through generations by word of mouth and documented scripts, with texts like the "Physica" of Hildegard von Bingen and the writings of Avicenna serving as foundational texts. However, it was not until the Renaissance that the systematic organization of pharmaceutical knowledge began to take shape. The dawn of the printing press facilitated the dissemination of medical texts, leading to the compilation of the first pharmacopoeias. One notable example is the "Cordiale" of Serapion the Younger, which provided detailed descriptions of medicinal flora and their curative effects. These early pharmacopoeias laid the groundwork for standardizing the preparation and dosage of medicinal substances, marking a crucial milestone in the professionalization of pharmacy.

B. Influence of Alchemy on the Search for the Philosopher's Stone and Elixir of Life

Alchemy, with its enigmatic pursuit of transmutation and the quest for the philosopher's stone, exerted a profound influence on the development of pharmacy during the medieval and Renaissance periods. While alchemy encompassed a wide array of metaphysical and symbolic elements, its practical applications intersected with the

realm of medicine and pharmacology. Central to alchemical doctrine was the belief in the existence of a universal panacea, often referred to as the elixir of life, capable of bestowing immortality and restoring youthfulness. Alchemists sought to unlock the secrets of nature's transformative powers through experimentation with various substances and chemical processes. While the alchemical quest for the philosopher's stone remained elusive, it spurred advancements in laboratory techniques and the refinement of pharmaceutical preparations.

Alchemy also supported the emergence of pharmacopoeias by introducing principles of distillation, sublimation, and extraction. Alchemical apparatuses such as alembics and retorts became essential tools in the crafting of health remedies, paving the path to the discovery of robust remedies like tinctures and essential oils. Despite the mystical connotations surrounding alchemy, its practical applications laid the groundwork for the emergence of modern chemistry and pharmacology.

C. Emergence of Early Forms of Pharmaceutical Regulation and Quality Control

As the demand for medicinal substances grew, concerns regarding the safety and efficacy of pharmaceutical preparations became increasingly pronounced. In response, various measures were enacted to regulate the production and sale of drugs, marking the genesis of pharmaceutical legislation. One notable example is the establishment of apothecaries' guilds, which sought to uphold standards of professional conduct and product quality. Guild regulations prescribed specific methods of preparation, storage, and labeling of pharmaceuticals, ensuring consistency and reliability in the dispensing of medicines. Additionally, governmental authorities began to issue edicts and decrees aimed at safeguarding public health by curbing the proliferation of counterfeit or adulterated drugs.

The development of pharmacopoeias also played a pivotal role in standardizing pharmaceutical practices and ensuring the quality of medicinal substances. Official pharmacopoeias, endorsed by medical authorities and governmental bodies, served as authoritative guides for pharmacists and physicians alike. These compendia delineated the composition, strength, and dosage of approved drugs, thereby enhancing transparency and accountability within the pharmaceutical sphere. Furthermore, advancements in analytical techniques, like the utilization of chemical assays and microscopy, enabled the detection of impurities and adulterants in pharmaceutical preparations. Pharmacists began to deploy thorough quality control protocols to assess the purity and potency of raw materials, thereby mitigating the risk of therapeutic failure or adverse effects.

4. The Rise of Modern Pharmacology: A Journey through Science, History, and Regulation ^[22-32]

The rise of modern pharmacology is a testament to human ingenuity, scientific inquiry, and the quest for better healthcare outcomes. From the scientific revolution and the birth of modern chemistry to the contributions of pioneering scientists like Paracelsus, Galen, and Avicenna, and the establishment of pharmaceutical companies and drug regulations, each milestone has shaped the landscape of pharmacology in profound ways. As we continue to untangle the intricacies of the human body and pioneer innovative treatments, it is imperative to uphold the principles of safety, efficacy, and ethical practice that underpin the field of modern pharmacology.

A. Scientific Revolution and the Birth of Modern Chemistry

The core of modern pharmacology stems from the Scientific Revolution of the 17th century, a period characterized by groundbreaking discoveries in various fields of science. Central to this revolution was the emergence of modern chemistry, which laid the foundation for understanding the composition and properties of matter. Visionaries like Robert Boyle, revered as the pioneer of modern chemistry, pioneered experimental methods and emphasized the importance of empirical evidence in scientific inquiry. Boyle's contributions, including his famous Boyle's Law, provided the framework for quantitative analysis in chemistry, enabling the systematic study of drugs and their effects on the body.

B. Contributions of Scientists like Paracelsus, Galen, and Avicenna to Pharmaceutical Knowledge

The journey of pharmacology is enriched by the invaluable contributions of eminent scientists and physicians throughout history. Paracelsus, a Swiss alchemist and physician, challenged the prevailing doctrines of his time and revolutionized the field of medicine with his emphasis on observation and experimentation. His concept of

"the dose makes the poison" laid the groundwork for modern toxicology and pharmacology, highlighting the importance of dosage in therapeutic interventions.

Galen, a prominent figure in ancient Greek medicine, exerted a profound influence on pharmaceutical knowledge through his extensive writings and empirical observations. His classification of drugs based on their properties and effects on the body provided a systematic framework for understanding pharmacology, which endured for centuries. Avicenna, an eminent Persian polymath of the Islamic Golden Age, made significant contributions to medicine and pharmacology through his seminal work, "The Canon of Medicine." Avicenna's comprehensive synthesis of medical knowledge from various cultures and his emphasis on evidence-based practice influenced generations of physicians and pharmacists, shaping the development of pharmacology in the medieval world and beyond.

C. Establishment of the Premier Pharmaceutical Companies and Drug Regulations

The upsurge of modern pharmacology was closely intertwined with the emergence of pharmaceutical companies and the need for regulatory oversight to ensure the safety and efficacy of medicinal products. In the 19th century, the Industrial Revolution catalyzed the mass production of pharmaceuticals, leading to the establishment of the first pharmaceutical companies such as Merck, Bayer, and Pfizer. These companies played a decisive role in advancing drug discovery and development, ushering in a phase of revolutionary ingenuity in pharmacology.

However, alongside the rapid expansion of the pharmaceutical industry came concerns about the quality and safety of medications. The infamous case of the Elixir Sulfanilamide tragedy in 1937, which resulted in the deaths of over 100 people due to a toxic solvent in a medicinal elixir, underscored the pressing necessity for Drug policy enforcement. In response, the United States Congress passed the Federal Food, Drug, and Cosmetic Act in 1938, establishing the modern regulatory framework for pharmaceuticals and ensuring rigorous testing and scrutiny of new pharmaceuticals prior to their commercialization.

5. Industrial Revolution and Drug Manufacturing ^[33-37]

The Industrial Revolution was a catalyst for profound changes in drug manufacturing, leading to significant advancements in pharmaceutical production and the growth of a global industry. Still these developments also led to substantial ethical predicament, particularly concerning the advertising, safety, and efficacy of drugs. The rise of patent medicines highlighted the need for regulatory oversight to protect consumers from harmful and ineffective products. The regulatory frameworks established in the early 20th century were pivotal in addressing these issues and continue to shape the ethical landscape of the pharmaceutical industry today. The balance between innovation, commercial interests, and ethical responsibility remains a critical aspect of the pharmaceutical industry. As technology continues to advance, ensuring the safety and efficacy of drugs while maintaining ethical standards in advertising and accessibility will be crucial for the continued trust and well-being of the public.

A. Impact of Technological Advancements on Pharmaceutical Production

The Industrial Revolution introduced machinery that revolutionized drug manufacturing. Before this period, pharmaceuticals were prepared manually by apothecaries and were largely inconsistent in quality and efficacy. With the advent of mechanized production, drugs could be produced in large quantities with greater uniformity.

Key technological advancements included the development of the steam engine, which powered factories, and innovations in chemical processes that allowed for the extraction and synthesis of active ingredients from natural sources. For example, the ability to isolate morphine from opium in the early 19th century was a direct result of improved chemical techniques and equipment. This led to more effective pain management options and laid the groundwork for the modern pharmaceutical industry. Moreover, advancements in encapsulation and tablet-making machinery enabled the production of standardized doses, improving the reliability and safety of medications. This mechanization also reduced the cost of drug production, making medicines more accessible to the general population.

B. Growth of the Pharmaceutical Industry and the Rise of Patent Medicines

The enhanced production capabilities fostered by the Industrial Revolution facilitated the rapid growth of the pharmaceutical industry. Companies like Merck, Bayer, and GlaxoSmithKline, which started as small apothecary shops or chemical companies, expanded their operations to become global pharmaceutical giants. The increased

availability of drugs and the economic benefits of large-scale production encouraged these companies to invest in research and development, leading to the discovery of new medications. Simultaneously, the rise of patent medicines became a significant phenomenon. Patent medicines were proprietary formulations that companies marketed aggressively, often claiming to cure a wide array of ailments. These products were typically sold without prescription and were one of the earliest forms of mass-marketed consumer goods. The most famous of these was Bayer's Aspirin, which became a household name. However, the lack of regulatory oversight meant that many patent medicines were ineffective or even harmful. Companies often included addictive substances like alcohol, opium, and cocaine in their formulations to ensure customer return. For instance, the infamous Coca-Cola originally contained coca leaf extract, which provided a cocaine-like stimulant effect.

C. Ethical Concerns Surrounding Advertising, Safety, and Efficacy of Drugs

The proliferation of patent medicines and the aggressive marketing tactics employed by pharmaceutical companies raised significant ethical concerns. One of the primary issues was the veracity of advertising claims. Many companies made exaggerated or false claims about the efficacy of their products, leading consumers to spend money on ineffective treatments. This practice was not merely deceptive but also dangerous, as it often delayed patients from seeking effective medical treatment. Safety was another major concern. Without proper regulation, many drugs on the market underwent no safety or efficacy testing. This led to numerous cases of poisoning, addiction, and death. The lack of labeling standards meant that consumers were unaware in light of the potential hazards linked to the drugs they were taking. The moral ramifications of these practices eventually led to public outcry and inclination for government intervention. This culminated in significant regulatory reforms, most notably the Pure Food and Drug Act of 1906 in the United States, targeting the most flagrant abuses in the industry. This act mandated proper labeling of ingredients and prohibited the sale of adulterated or misbranded drugs, laying the foundation for modern pharmaceutical regulation.

Further advancements in drug safety and efficacy were driven by the dominant elite of organizations like the Food and Drug Administration (FDA) in 1930, mandated with overseeing the safety of food and drugs. The introduction of rigorous clinical trials and approval processes ensured that new medications were both safe and effective before reaching the market. In contemporary times, ethical concerns in the pharmaceutical industry continue to evolve. Issues such as drug pricing, access to medications, and the influence of pharmaceutical companies on medical practice remain at the forefront of ethical debates. The industry's role in the opioid crisis, where aggressive marketing and misleading information about the addictiveness of opioids contributed to widespread addiction, is a stark reminder of the potential consequences of unethical practices.

6. Twentieth Century: Pharmacological Innovations and Ethical Challenges [38-50]

The twentieth century was a period of unprecedented growth and innovation in pharmacology, marked by the discovery of life-saving antibiotics, vaccines, and other essential medications. Conversely, these advancements were not without ethical challenges. The Thalidomide tragedy exposed critical flaws in drug regulation and testing, leading to more stringent safety measures and regulatory reforms. Simultaneously, the aggressive marketing practices and conflicts of interest within the pharmaceutical industry highlighted the need for greater transparency and ethical oversight. These historical lessons continue to shape contemporary pharmacological practices and policies, emphasizing the criticality of integrating innovation with duty to guarantee patient safety and inspire confidence in medical advancement.

A. Discovery of Antibiotics, Vaccines, and Other Groundbreaking Medications

The twentieth century witnessed remarkable advancements in medical science, with antibiotics and vaccines standing out as some of the most impactful discoveries. The introduction of antibiotics, beginning with Alexander Fleming's discovery of penicillin in 1928, revolutionized the treatment of bacterial infections. Penicillin's ability to effectively combat a wide range of bacterial infections saved countless lives and paved the way for the development of other antibiotics, such as streptomycin, tetracycline, and erythromycin. Vaccines also saw significant progress during this period. The development of the polio vaccine by Jonas Salk in 1955 and the oral polio vaccine by Albert Sabin in 1961 were monumental achievements. These vaccines led to a dramatic reduction in polio cases worldwide and brought the world closer to eradicating the disease. Additionally, the development of vaccines for measles, mumps, and rubella (MMR) in the 1960s and 1970s further exemplified the era's strides

in preventive medicine. Beyond antibiotics and vaccines, other medications such as insulin, discovered by Frederick Banting and Charles Best in 1921, transformed the management of diabetes, significantly improving the quality of life for patients. The introduction of psychotropic drugs like chlorpromazine in the 1950s revolutionized the treatment of mental health disorders, marking the beginning of modern psychopharmacology.

B. Thalidomide Tragedy and Its Impact on Drug Regulation and Testing

While the twentieth century's pharmacological innovations brought immense benefits, they also highlighted the critical need for stringent drug regulation and testing. The Thalidomide tragedy of the late 1950s and early 1960s stands as a stark reminder of this necessity. Thalidomide, initially marketed as a sedative and later for treating morning sickness in pregnant women, led to severe birth defects in thousands of children across Europe and other parts of the world. The widespread congenital abnormalities, including limb deformities, caused by Thalidomide prompted a global outcry and underscored the inadequacies in the drug approval process. In response, many countries implemented more rigorous drug testing and approval protocols. In the United States, the tragedy led to the passage of the Kefauver-Harris Amendment in 1962, which strengthened the FDA's authority to regulate drugs. This legislation mandated more comprehensive clinical trials, informed consent from participants, and stringent reporting of adverse effects. The Thalidomide disaster also highlighted the importance of pharmacovigilance the continuous monitoring of drugs after they reach the market. This tragedy fundamentally changed the way drugs are tested and regulated, prioritizing patient safety and efficacy before a drug can be widely distributed.

C. Controversies Surrounding Pharmaceutical Marketing Practices and Conflicts of Interest

The rapid expansion of the pharmaceutical industry in the twentieth century brought with it significant controversies, particularly regarding marketing practices and conflicts of interest. Pharmaceutical companies have been criticized for aggressive marketing tactics, which often prioritize profit over patient welfare. These tactics include the promotion of drugs for off-label uses, direct-to-consumer advertising, and the provision of incentives to healthcare providers for prescribing specific medications. One notable example is the opioid crisis in the United States, which has been partially attributed to misleading marketing practices by pharmaceutical companies. Companies like Purdue Pharma aggressively marketed opioid painkillers such as OxyContin, downplaying their addictive potential and contributing to widespread misuse and addiction. This crisis has resulted in significant public health challenges and legal repercussions for the involved companies.

Conflicts of interest also pose substantial ethical concerns. The close financial relationships between pharmaceutical companies and medical professionals can influence clinical decision-making and research outcomes. For instance, studies funded by pharmaceutical companies are more likely to report favorable results for their products compared to independently funded research. This bias can undermine the credibility of scientific research and the trust of the public in medical professionals and treatments. To address these issues, various measures have been implemented. The Physician Payments Sunshine Act in the United States, part of the Affordable Care Act, requires transparency regarding financial relationships between healthcare providers and pharmaceutical companies. This legislation aims to reduce conflicts of interest by making such interactions public knowledge, thereby encouraging more ethical practices in the industry.

7. Contemporary Issues in Pharmaceuticals and Ethics [51-59]

The pharmaceutical industry stands at the crossroads of innovation and ethics, with contemporary issues challenging stakeholders to balance commercial interests with public health imperatives. Globalization has expanded access to medicines but also highlighted persistent inequities. The debate over intellectual property rights underscores the need for a balanced approach that encourages innovation while ensuring affordability. Ethical considerations in clinical trials, drug pricing, and healthcare disparities further complicate the landscape, demanding vigilant oversight and equitable policies. Moving forward, collaborative efforts among governments, international organizations, and pharmaceutical companies are crucial to address these challenges. By prioritizing ethical principles and equitable access, the industry can contribute to a healthier and more just global society.

A. Globalization of the Pharmaceutical Industry and Access to Essential Medicines

Globalization has significantly transformed the pharmaceutical industry, leading to increased production and distribution of drugs worldwide. This interconnectedness, however, presents both opportunities and challenges in ensuring access to essential medicines. On one hand, globalization facilitates the spread of medical innovations,

making cutting-edge treatments more accessible globally. It also enables pharmaceutical companies to leverage international markets, thus potentially lowering costs through economies of scale. On the other hand, disparities in access to essential medicines persist, particularly in low- and middle-income countries (LMICs). Issues such as supply chain disruptions, regulatory barriers, and economic inequities often limit the availability of critical drugs in these regions. Efforts to improve global access include initiatives by organizations like the World Health Organization (WHO), which advocates for policies that promote affordable and equitable access to medicines. However, achieving this goal requires balancing the interests of pharmaceutical companies with the needs of underserved populations. Strategies such as differential pricing, voluntary licensing, and support for local manufacturing can help bridge these gaps.

B. Debate over Intellectual Property Rights and Generic Drug Availability

Intellectual property (IP) rights, particularly patents, play a crucial role in the pharmaceutical industry by incentivizing innovation. Patents grant companies exclusive rights to manufacture and sell new drugs, allowing them to recoup research and development (R&D) costs. However, this exclusivity often leads to high drug prices, restricting access to life-saving medications, especially in poorer nations. The debate over IP rights centers on finding a balance between rewarding innovation and ensuring public health needs are met. Critics argue that stringent IP protections hinder the availability of affordable generic drugs, which are essential for treating widespread health conditions in resource-limited settings. For instance, the high cost of antiretroviral drugs in the early 2000s sparked global outrage and led to significant policy changes to improve access to HIV/AIDS treatments. Compulsory licensing is one mechanism that can address this issue. It allows governments to authorize the production of generic versions of patented drugs without the consent of the patent holder, typically under conditions of public health emergencies. The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement and its subsequent amendments provide a legal framework for such measures, although their implementation remains contentious and politically sensitive.

C. Ethical Considerations in Clinical Trials, Drug Pricing, and Healthcare Disparities

Ethical issues in the pharmaceutical industry extend to clinical trials, drug pricing, and the broader context of healthcare disparities.

Clinical Trials: Conducting clinical trials ethically is paramount to ensuring the safety and rights of participants. This includes obtaining informed consent, ensuring transparency in reporting results, and conducting trials in accordance with ethical standards. However, outsourcing clinical trials to LMICs has raised concerns about exploitation and ethical oversight. These regions often have less stringent regulatory environments, which can lead to ethical breaches and insufficient protection for trial participants.

Drug Pricing: The high cost of new medications remains a contentious ethical issue. Pharmaceutical companies justify high prices by citing the substantial investment required for R&D, which includes not only the cost of successful drugs but also the expense of numerous failed projects. Nonetheless, exorbitant drug prices can lead to significant financial burdens on patients and healthcare systems, exacerbating inequities in access to treatment.

Healthcare Disparities: The inequitable distribution of healthcare resources and access to medicines is a critical ethical concern. Factors such as socioeconomic status, geographic location, and healthcare infrastructure contribute to disparities in health outcomes. For example, the stark differences in access to COVID-19 vaccines between high-income countries and LMICs highlighted the profound inequities in global health.

Addressing these ethical issues requires multifaceted approaches. Regulatory frameworks must be strengthened to ensure ethical conduct in clinical trials, and international cooperation is essential to make lifesaving drugs more affordable and accessible. Policies promoting transparency in drug pricing and innovative financing mechanisms can also help mitigate healthcare disparities.

8. Future Perspectives and Challenges ^[60-65]

The future of pharmaceutical development is bright, with advances in personalized medicine, biotechnology, and gene therapy poised to transform healthcare. However, realizing this potential requires careful consideration of the ethical implications of new technologies and the development of robust bioethical and regulatory frameworks. By addressing these challenges, we can ensure that these innovations benefit all patients and contribute to a more equitable and effective healthcare system.

A. Advances in Personalized Medicine, Biotechnology, and Gene Therapy

The landscape of healthcare is rapidly evolving, driven by remarkable advancements in personalized medicine, biotechnology, and gene therapy. These innovations promise to revolutionize the way we understand and treat diseases, offering unprecedented levels of customization and precision. Personalized medicine, also known as precision medicine, tailors medical treatment to the individual characteristics of each patient. This approach relies heavily on genetic, environmental, and lifestyle factors to determine the most effective treatment strategies. The rise of genomic sequencing technologies has been pivotal, allowing for the identification of genetic mutations and variations that contribute to disease. This enables healthcare providers to predict disease susceptibility, customize treatments, and even prevent illnesses before they develop. For instance, targeted therapies for cancer, such as those for breast cancer with HER2 gene mutations, exemplify the power of personalized medicine in improving patient outcomes. Biotechnology, the application of biological systems and organisms to develop products and technologies, is another critical driver of change. Innovations in this field include the development of biologics, such as monoclonal antibodies and recombinant proteins, which have become essential in treating a range of conditions from autoimmune diseases to cancers. Additionally, advances in CRISPR-Cas9 and other gene-editing technologies are opening new frontiers in biotechnology, offering the potential to correct genetic defects at their source.

Gene therapy, which involves altering the genetic material within a patient's cells to treat or prevent disease, has seen groundbreaking progress. Recent FDA approvals of gene therapies for conditions like spinal muscular atrophy (SMA) and inherited retinal diseases highlight the transformative potential of these treatments. By directly addressing the genetic root causes of diseases, gene therapy offers hope for conditions previously deemed untreatable.

However, despite these advances, significant challenges remain. The high cost of personalized medicine and gene therapy poses a barrier to widespread adoption. Ensuring equitable access to these treatments is a critical concern, as is the need for robust clinical evidence to support their efficacy and safety. Additionally, the complexity of developing and manufacturing biotechnological products requires substantial investment and expertise.

B. Ethical Implications of Emerging Technologies Like AI in Drug Discovery and Precision Medicine

As emerging technologies like artificial intelligence (AI) become integral to drug discovery and precision medicine, they bring with them a host of ethical implications that must be carefully considered. AI has the potential to accelerate drug discovery by analyzing vast datasets to identify potential drug candidates more efficiently than traditional methods. Machine learning algorithms can predict how drugs will interact with targets in the body, optimize clinical trial designs, and even personalize treatment plans based on individual patient data. However, the integration of AI into healthcare raises several ethical concerns. One major concern is data privacy. AI systems require access to large amounts of patient data to function effectively, raising questions about how this data is collected, stored, and shared. Ensuring patient consent and protecting sensitive health information from breaches are paramount.

Bias in AI algorithms is another critical issue. AI systems are only as good as the data they are trained on. If the training data is biased or unrepresentative, the AI's predictions and recommendations can perpetuate existing disparities in healthcare. For example, if an AI system is trained predominantly on data from a specific population, it may not perform as well for individuals from underrepresented groups, leading to inequities in treatment. The transparency and accountability of AI systems also pose ethical challenges. The "black box" nature of some AI algorithms makes it difficult to understand how they arrive at specific conclusions or recommendations. This lack of transparency can undermine trust in AI-driven healthcare solutions and complicate efforts to validate and regulate these technologies.

C. The Role of Bioethics and Regulatory Frameworks in Shaping the Future of Pharmaceutical Development

Bioethics and regulatory frameworks play a crucial role in guiding the development and application of new pharmaceutical technologies. As personalized medicine, biotechnology, and gene therapy continue to advance, these frameworks must evolve to address the complex ethical and safety issues that arise. Bioethics provides a foundation for evaluating the moral implications of new medical technologies. It emphasizes principles such as

autonomy, beneficence, non-maleficence, and justice. In the context of personalized medicine and gene therapy, bioethics helps ensure that patient rights are respected, that treatments provide more benefit than harm, and that access to new therapies is equitable.

Regulatory agencies, such as the FDA in the United States and the EMA in Europe, are responsible for ensuring the safety and efficacy of new drugs and therapies. As the pace of innovation accelerates, these agencies face the challenge of keeping their regulatory frameworks up to date. This includes developing guidelines for the use of AI in drug discovery, setting standards for the validation and approval of gene therapies, and addressing the ethical use of genetic information. One area where regulatory frameworks are particularly crucial is in the oversight of clinical trials. Traditional clinical trial models may not be well-suited to personalized medicine, where treatments are tailored to individual genetic profiles. Adaptive trial designs, which allow for modifications based on interim results, are becoming more common but require careful regulatory oversight to ensure they remain scientifically rigorous and ethically sound.

In addition to formal regulations, ethical oversight bodies such as institutional review boards (IRBs) play a key role in protecting patient welfare in research. These bodies review study protocols to ensure that they comply with ethical standards and that participants are adequately informed about the risks and benefits of the research. Looking ahead, the continued evolution of bioethics and regulatory frameworks will be essential to navigate the challenges posed by rapidly advancing medical technologies. Ensuring that these frameworks are flexible yet robust enough to address emerging issues will be critical to realizing the full potential of personalized medicine, biotechnology, and gene therapy while safeguarding patient welfare and societal trust.

9. Conclusion [66- 70]

A. Summary of Key Historical Milestones and Ethical Considerations in Pharmaceuticals

The pharmaceutical industry has a storied history marked by significant milestones and complex ethical considerations. One of the earliest milestones was the development of vaccines, starting with Edward Jenner's smallpox vaccine in 1796. This breakthrough not only set the stage for the field of immunology but also highlighted the potential of medical science to eradicate diseases. However, this period also sparked ethical debates about vaccine safety and public consent. The 20th century witnessed a surge in pharmaceutical advancements, with the discovery of penicillin by Alexander Fleming in 1928 revolutionizing the treatment of bacterial infections. This period also saw the introduction of rigorous clinical trials and regulatory frameworks, such as the establishment of the Food and Drug Administration (FDA) in 1906. These measures were designed to ensure drug safety and efficacy, thereby addressing growing public concerns about the potential for harm and exploitation in the rapidly expanding industry.

One of the most pivotal moments in pharmaceutical ethics was the thalidomide tragedy of the late 1950s and early 1960s. Marketed as a safe sedative for pregnant women, thalidomide led to severe birth defects in thousands of children, prompting a global overhaul of drug approval processes and the implementation of stricter regulations. This tragedy underscored the need for rigorous testing and transparency, shaping modern ethical standards in drug development and marketing. In recent decades, the rise of biotechnology and personalized medicine has opened new frontiers in treatment but has also introduced complex ethical dilemmas. For instance, the advent of gene therapy and CRISPR technology holds immense promise for curing genetic disorders but raises questions about genetic modification and potential long-term consequences. Additionally, the high cost of innovative treatments has sparked debates about access to life-saving drugs and the ethical responsibilities of pharmaceutical companies to balance profit with public health.

B. Reflection on the Evolving Relationship Between Science, Medicine, and Ethics

The relationship between science, medicine, and ethics in the pharmaceutical industry has evolved significantly over time, often shaped by the interplay of scientific breakthroughs and societal values. In the early days of modern medicine, the primary focus was on discovering new treatments and cures, with less attention to the ethical implications of medical experimentation and patient consent. However, as the industry matured, the need for ethical oversight became increasingly apparent. The mid-20th century marked a turning point, as public awareness of medical ethics grew in response to high-profile scandals and tragedies. The Nuremberg Code, established in 1947 in the aftermath of World War II, set foundational principles for ethical medical research, emphasizing informed consent and the necessity of avoiding unnecessary suffering. This code laid the groundwork for later

ethical guidelines, such as the Declaration of Helsinki, which further refined ethical standards for medical research involving human subjects.

In contemporary times, the relationship between science, medicine, and ethics has become even more intricate. The rapid pace of scientific advancements, particularly in genomics, biotechnology, and artificial intelligence, has created new ethical challenges. Issues such as data privacy in genetic research, the use of AI in drug development, and the equitable distribution of advanced therapies require ongoing ethical scrutiny and adaptive regulatory frameworks. Moreover, the COVID-19 pandemic has highlighted the critical importance of balancing scientific innovation with ethical considerations. The accelerated development and distribution of COVID-19 vaccines demonstrated the potential for scientific collaboration and regulatory flexibility. However, it also raised ethical questions about global vaccine equity, transparency in clinical trial data, and the management of vaccine hesitancy. These challenges underscore the need for an ongoing dialogue between scientists, ethicists, policymakers, and the public to navigate the complex landscape of modern pharmaceuticals.

C. Call to Action for Continued Dialogue and Responsible Decision-Making in the Pharmaceutical Industry

As we look to the future, it is imperative that the pharmaceutical industry continues to engage in responsible decision-making and fosters an open dialogue with all stakeholders. The ethical landscape of pharmaceuticals is continually evolving, necessitating a proactive approach to addressing emerging challenges and ensuring that scientific progress aligns with societal values. Firstly, there must be a commitment to transparency and accountability in all aspects of drug development and marketing. Pharmaceutical companies should prioritize clear communication about the benefits and risks of new treatments, ensuring that patients and healthcare providers have access to accurate and comprehensive information. This includes transparency in clinical trial results, pricing strategies, and potential conflicts of interest. Secondly, the industry must address the issue of access to medicines, particularly in low- and middle-income countries. The development of life-saving drugs is only meaningful if they are accessible to those in need. This requires innovative solutions to reduce costs, such as differential pricing, public-private partnerships, and the support of generic drug production. It also entails advocating for international policies that promote equitable access to essential medicines. Thirdly, ethical considerations must be integrated into the early stages of scientific research and development. This involves fostering a culture of ethical awareness among researchers and ensuring that ethical review boards are equipped to evaluate the implications of emerging technologies. Collaborative efforts between ethicists, scientists, and policymakers are crucial in developing guidelines that address new ethical dilemmas, such as those posed by gene editing and artificial intelligence. Finally, there must be a continuous effort to engage the public in discussions about pharmaceutical ethics. Public trust is essential for the success of medical interventions, and this trust is built through transparency, education, and meaningful dialogue. Engaging patients, advocacy groups, and the broader community in conversations about the ethical dimensions of drug development can help to align scientific progress with public expectations and values.

In conclusion, the pharmaceutical industry stands at the intersection of science, medicine, and ethics, with a responsibility to ensure that its advancements benefit society as a whole. By embracing transparency, promoting equitable access to medicines, integrating ethical considerations into research, and fostering public dialogue, the industry can navigate the complex ethical landscape and continue to contribute to global health and well-being.

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