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Viagra's rise above women's health issues: An analysis of the social and political influences on drug approvals in the United States and Japan

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Abstract

In the United States, Viagra was approved in less than 6 months of its application to the Food and Drug Administration, while the medical abortion pill was approved 4 years after its application, and 17 years after research was first permitted. Congruently, the Ministry of Health in Japan legalized Viagra in 6 months, while oral contraceptives were approved 35 years after the ministry received initial applications. The pharmaceutical review agencies in each country are founded on safety and efficacy standards, in which objective decisions arise from science and clinical investigations. Analyses of these recent drug approvals demonstrate that conclusions may not have been based simply on science and health concerns. Instead, agency actions and application of pharmaceutical law appear to have been influenced by social and political pressures surrounding the products under scrutiny. Pharmaceutical regulations were effectively ignored or manipulated in the United States during the review process for medical abortion, and were applied inconsistently in Japan—ultimately yielding results that happened to conform to contemporary sociopolitical beliefs. Such disregard of legislation holds serious ramifications for public health, national consumer trust and the pharmaceutical industry. It is imperative that external pressures remain outside the scope of drug approval processes.

Keywords: Pharmaceuticals; Regulation; Drug approval; Viagra; USA; Japan; Medical abortion; Oral contraception

Introduction

The introduction of Viagra revolutionized the pharmaceutical industry and bedroom activity worldwide. Pharmaceutical review boards accelerated the drug's approval so that consumers could take advantage of this new product as quickly as possible. Certain products pertaining to women's sexual health, however, were not met with comparable enthusiasm. In the United States, where Viagra was approved in less than 6 months of its application to the Food and Drug Administration (FDA), the medical abortion pill was approved 4 years after its application, and 17 years after research was even permitted. Congruently, Japan approved its first low-dose hormonal method of contraception in June of 1999, 35 years after oral contraceptives were introduced in western nations and more than 9 years after applications were submitted to the Ministry of Health (MOH). In stark contrast, Viagra was available in Japan 6 months after its drug application was submitted.

An examination of national pharmaceutical laws demonstrates that both the United States' FDA and the Japanese MOH offered procedural discrepancies

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through the hastened approvals of Viagra and delayed approvals of pharmacological abortion and oral contraception. Regulations were interpreted in such a way that ultimately conformed to contemporary political and social pressures.

Both the FDA and the MOH are mandated to grant drug approvals according to safety and efficacy, and claim to base these approvals on science and medical knowledge. Sociopolitical pressures can undermine this claim, damaging public health and the pharmaceutical industry. Such forces should not affect agency decisions; instead, social and political messages should be redirected to influence use of a product or to amend laws that govern agency procedures that seem unjust. Preventing abuse of drug review systems would ensure safety and objectivity for health professionals and consumers.

Background

Researchers and social historians have often commented on the intrinsic link between science and politics. Scientific theories and paradigms have historically shifted in the face of society and politics, just as social and political concerns have been dictated by contemporary scientific thought. This inevitable association should not, however, go unchecked as public health and security can suffer as a result. In the United States, the George W. Bush administration has been criticized for allowing political agendas to influence both the application and use of science and legislation. Officials have been accused of distorting the intent of federal advisory committees to correspond to sociopolitical ideologies by appointing experts based on social convictions rather than impartial scientific merit (Kennedy, 2003; Reppert, 2004; Steinbrook, 2004; Union of Concerned Scientists, 2004).

Drug regulatory bodies are no exception to criticism. Experts often discuss the necessity to preserve the strength and stability of pharmaceutical review boards around the world (Abraham, 2002; Dag Hammarskjöld Foundation, 1995; Effective Medicines Regulations, 2003; Ratanawijitrasin & Wondemagegnehu, 2002; Wondemagegnehu, 1999). Improper influences on the application and interpretation of science can weaken these regulatory bodies, and can create bias and undermine public interest (Abraham, 1995, 2002). Accusations of inappropriate bias on FDA decisions have emerged in recent years. An April 2004 comment in the New England Journal of Medicine on the FDA denial of over-the-counter emergency contraception criticizes how sociopolitical pressures motivated agency decisions rather than science (Drazen, Greene, & Wood, 2004); and the influence of pharmaceutical companies over the objectivity of agency decisions through money and political clout has been repeatedly explored (Abraham, 2002; Bean, 2003; Drazen et al., 2004; Willman, 2000).

The case for FDA and international drug regulatory procedures to remain robust and reliable is strong. This article supports this theory regarding the application and execution of supposed objective pharmaceutical laws and standards—an area most crucial to preserve and protect from political distortions.

Methodology

Drug approval processes in the United States and Japan were chosen because of the integral roles these countries play in the international pharmaceutical community. Both nations are prominent leaders in many global drug-related organizations such as the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and numerous World Health Organization committees. As such, they set both direct and indirect examples for poor and transitional countries on the development or revision of pharmaceutical review boards. Therefore, the implications of drug regulatory manipulations in these countries are profound.

The unequal treatments between the pairs of pharmaceuticals under scrutiny offer interesting comparisons. Viagra and these corresponding female-centered drugs were, and still are, highly publicized pharmaceuticals. The politics behind these approvals, along with the conditions they address, are rather charged and controversial. As a result, they offer an excellent opportunity to highlight discrepancies and to examine whether there has been political abuse of regulation.

This analysis primarily relies upon FDA approval documents and medical guides, FDA published regulations and reports, federal bills and statutes, and Japanese published pharmaceutical regulations. Additional information is extracted from newspaper and journal articles. This article will first describe respective pharmaceutical laws during the approval periods under investigation. Next, through a historical documentation of how pharmaceutical laws were applied in each case, regulatory and legal discrepancies will be exposed. This article will then offer possible theories as to why laws were not applied equally based on contextual facts. Specific focus will remain on social and political climates and their effects on the application of drug laws.

United States

FDA approval of new drugs

Based on clinical tests and scientific studies, the Center for Drug Evaluation and Research within the FDA decides whether a drug is safe and effective, and