

# Pharmacopolitics, Implications and Implementation in Clinical Studies

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## Definition of Pharmacopolitics

Prior to defining pharmacopolitics, one may wonder about this odd associations and relevancy of terminology. The word politics denotes articulating and resolving conflicts within society without recourse to physical violence [1]. Pharmaco stems from the Greek name Pharmakon/Pharmacon which entail active ingredients/drug or medicine and is pertaining to pharmaceuticals and pharmacy sciences. Hence, the word pharmacopolitics joined the politics to medicines-drugs-pharmaceuticals to clarify the study of drug safety and efficacy (difficulties and solutions) in relation to societal priorities, controversies, health budgets and associated costs. This juxtaposition of the two words emphasizes the significance and impact of pharmaceuticals on health decisions, health political conflicts and societal health needs and priorities.

## Background

The pharmacy profession sub specialties are emerging every decade with an escalated velocity in last 20 years. Since the father of pharmacy the

subject of basic drug sciences i.e. applied pharmacology, a plethora of pharmaceutical specialties has come forward such as pharmacokinetics, pharmacotherapeutics, pharmacogenetics, pharmacogenomics, pharmacoepidemiology, pharmacoinformatics, pharmacovigilance and pharmaco economics. Recently, a promising interest has been arising in the new sub specialty refer to as pharmacopolitics [2,3].

Pharmacopolitics is alarmed, with finding an appropriate equilibrium between the risks and benefits of drug therapy (safety and cost-effectiveness) or risk-benefit ratio, with resolving the competing claims of profit for the pharmaceutical industry and the broad public interest, and with decisive pattern of how society should attempt to control the use of pharmaceuticals.

## The Current Status of Pharmacopolitics

The increase in populations around the globe leads to inadequate implication of global politics, finance and administration. These high profile disparities also directly or indirectly affected the health care system such as inadequate pharmaceutical costs, poor drug regulations, and shortage medical supplies. For example, pharmaceutical firms in developed countries like United States of America (USA) and some European countries defend drug costs by explaining the expenditures during their clinical trials. On the other hand, due to these divergences many developing countries (unclear in many poor nations) fails to meet the health care needs, affordable to purchase the drugs, and these drug-politics were not even understood by common citizens [4]. Global uniformity and standardization of the drug pricing, drug testing and regulations is highly needed to the change in a variety of less visibly political settings.

In recent years, there was huge number of consumers demanding the impact of disease and appropriateness of competing treatments has broadened the attention in the medical politics and governmental health agencies. These perspectives also shed light on changing new arenas in drug policies. In this context, regulatory agencies has a key role to overseeing the pharmaceutical industry in developing and maintaining the ways by demanding premarket testing and formal application for market approval [5]. New drugs achieve marketable status only if the manufacturer complies with government guidelines for testing and provides authorities with evidence of their safety and efficacy. These recent changes lead a massive research and development (RD) investments coupled with reaching the citizens expectations in fixing a wide variety of diseases, disorders, and discomforts.

## The International Perspectives

Over the past decade, multinational pharmaceutical companies have encouraged the mergers and greater cross-national RD investments. All these firms seek to market their medicines across the globe and work with physicians in a variety of settings to meet regulatory demands. During Nineteenth century, the United States-Food and Drug Administration (US-FDA) has lead a new foundation in expanding its authority through a sequence of legislative and regulatory initiatives, physicians authorities to define drug safety and ability to control the use of pharmaceuticals. No one group can easily claim a monopoly to represent patients in political settings [6]. Pharmaceutical drug regulations in the USA thus are associated with significant renegotiation of authority among the key actors in medical policy. Thus, US-FDA plays a far greater role in all aspects of drug testing and market surveillance.

Over the course of the last decade, European Federation of Pharmaceutical Industries and Associations, FDA, Pharmaceutical Research and Manufacturers of America, Japan's Ministry of Health, Labor and Welfare, and Japan Pharmaceutical Manufacturers have worked closely to create harmonized procedures for the global introduction of new drugs by a series of meetings, formally known as the "International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use" (ICH). ICH's primary purpose is to harmonize technical guidelines and requirements for medicinal drug registrations [7]. The industry and regulators have found their interests converging over the last decade with a mutual desire to reduce the use of "human, animal, and material resources"

as they work to eliminate unnecessary delay in the global development and registration of new drugs.

Since clinical trials now consume over half of drug companies' RD spending, manufacturers are highly motivated to cut down on the quantity and variety of tests required by national regulatory agencies. The long-term goal of ICH, however, is far more ambitious than to simply rationalize drug approvals and to create a world in which only one set of research trials is performed before the global marketing of a new drug can take place [8]. In their vision of the future, data produced in this crucial experiment (or centrally coordinated set of clinical trials) will be reviewed using uniform standards. Recognizing the near-impossibility of dismantling well-established regulatory agencies, ICH hopes nonetheless that uniform product submissions will lead to the same conclusions regarding a drug's "approvability" around the world.

## Conclusions

With the increased pharmaceutical costs and expensive developed new therapeutic drug entities, a growing concern about developing a uniform standard of clinical trials, marketing and regulatory reviews is highly warranted. The science of pharmacopolitics will continue to delve deeper the issues of public concerns. Pharmacopolitics research taking into consideration the consumers' opinion and respective involved authorities.

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