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BOOK REVIEW

THE TRUTH PILL: THE MYTH OF DRUG REGULATION IN INDIA BYDINESH S. THAKUR AND PRASHANT REDDY T.

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The Book titled "The Truth Pill - The Myth of Drug Regulation in India" runs into 11 chapters. The book begins with a Prologue: An Epidemic of DEG Poisoning and Regulatory Failure. The author clearly explains about Indian Companies quite often fail to test either the raw materials or the final formulationbefore shipping it to the market. This is despite having Good Manufacturing Practices (GMP) being prescribed under Indian law requiring mandatory testing of both the raw material before it is used in production and the final formulation before it is shipped to the market. Further, the author throws light on the incident of the mass poisoning in Jammu. The Himachal Pradesh Drug Control Administration (HPDCA) which has jurisdiction over the manufacturer of the alleged adulterated cough syrup-Digital Vision alleged before the Himachal Pradesh High Court that Digital Vision lacked an appropriate facility to test the furnished information for DEG contamination and that the analysis report from Digital Visions quality control department indicating the absence of DEG in dangerous quantities was misleading. Hence, author states there can be no cure without a diagnosis.

In the first chapter titled as The Birth of Modern Medicine and Drug Regulation, the author discusses about the birth of the 'cell and germ theory' and the nation's steps to regulate the science of drugs. The German and French regulatory models were path-breaking because they ensured perhaps for the first time in history, an assurance from the state regarding the quality of a drug that was being supplied to patients. The deaths of 13 children in St Louis, Missouri and Camden were the first instances of mass deaths from mass manufactured drugs and served as a reminder that these new life saving drugs could be dangerous if not manufactured and tested properly in completely sterilized premises. Further, the author suggests that if a country is governed by poorly designed and enforced drug regulatory system, people will die. The pharmaceutical industry cannot be trusted to regulate itself.

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The second chapter titled Controlling the Craze for Medicinal Drugs in Colonial India wherein detailed discussion is made by analyzing the Chopra Committee-The Report of the Drugs Enquiry Committee,1930-31. Many of the issues during the debate on Sir Jaffers motion in 1927 were not addressed by the new law. The present chapter covers the issues such as the lack of requirement for the pharmaceutical industry to provide any clinical proof of safety and efficacy of new drugs, lack of regulation of traditional medicinal industries like Ayurveda and Unani, exaggerated and misleading advertisements by the pharmaceutical industry, and finally, the unhealthy nexus between the pharmaceutical industry and the medical practitioners.

The third chapter titled Of Botched Investigations, Dodgy Prosecution Guidelines, and Lenient Judgeswhere the author has made intensive discussion on the drugs declared as "Not of Standard Quality (NSQ)". It is obvious that a NSQ drug poses a danger to public health, Indian Courts are known to have been very lenient. Under the Drugs and Cosmetics Rules, 1945, Pharmaceutical companies manufacturing drugs must have the manufacturing license. In case of Krebs Biochemicals, Andhra Pradesh court convicted the Managing Director for the manufacturing and sale of drug without obtaining valid a license in violation of section 18(c) of the Drugs and Cosmetics Act in 2019. Further, the Managing Director was sentenced to prison for a period of one year and a fine of Rs.20000.The author rightly pointed out that while acquittals and lenient sentencing discussed in the many cases and more worrying fact is only a very small percentage of cases where the system detects NSQ drugs are actually prosecuted by the drug inspectors. The author in the present chapter makes critical analysis of The Drugs and Cosmetics Act 1940 provisions and identifies the bottlenecks for implementation.

For the state of Karnataka, the authors managed to get data from the Karnataka Drug Control Department under RTI for a period of seven years from 2015 to 2021. These included prosecutions filed against manufacturers of NSQ drugs, pharmacists and a small number of cases pertaining to violation of price control laws. Similarly, authors got around 30 judgments from Tamil Nadu in prosecutions against pharmaceutical companies on the charges of manufacturing NSQ drugs. The lenient sentencing in prosecutions under the DCA 1940 will require the public prosecutors to push back against such sentencing practices by judicial magistrate and if required challenging such decisions before the higher courts. For this to happen, state governments must have the political will to order prosecutors to demand stricter sentencing or at least compliance with the minimum sentencing requirements in the law.

The fourth chapter is exclusively devoted for the discussion on Of Glass Particles and Bacterial Endotoxins. In the present chapter the author enumerates that one of the likely reasons for Indian pharmaceutical companies ignoring Good Manufacturing Practices (GMP) compliance in India is because the Indian Drug Regulatory machinery has always been more focused on surveilling and testing the quality of drugs sold in the market. Many states simply do not have sufficiently well-equipped laboratories and trained analysts to conduct a full pharmacopeial analysis of samples procured by drug inspectors from the market. Trying to protect public health through market surveillance is less rigorous than focusing on GMP compliance during the manufacturing process. Authors had filed applications under RTI asking whether they had specific guidelines in place instructing their drug inspectors on the type of drugs from the market for testing purpose. The authors finally conclude the chapter highlighting that the state laboratories are required to conduct a critical test called 'impurity testing'. Even the data available on the XLN website is not structured and there is no consistency in the way data is catalogued, making it difficult to perform any meaningful analysis.

The fifth chapter titled New Drugs and The Persistent Insolence of the Central Drugs Standards Control Organisation(CDSCO), where the author explains about the pharmaceutical industry's response to the pandemic by investing in the creation of new vaccines as well as in the creation of new drugs and re-purposing existing treatments to treat COVID-19 patients. There is absence of evidence-based medicine in India -wherein the individual Indian Doctors have been making an effort to spread the principles of evidence-based medicine, but institutional push appears to be lacking.

In the sixth chapter titled as Can Made in India Generic Medicine Be Trusted?,the author proposes that the government should introduce a mandatory labelling requirement for all drugs sold in India indicating whether the drug in question has successfully undergone bioequivalence and stability testing. Such a labeling requirement combined with a mandatory requirement of public disclosure will give doctors the necessary information to ascertain the trustworthy formulations for themselves.

The seventh chapter- The Losing Battle to Regulate Traditional Indian Medicine, conveys that the Ayurvedic product which demonstrates the potential to cure or treat a disease or ailment, it should go through the same regulatory pathways as any other new drug i.e. a rigorous three phased double blinded RCT to establish its safety and efficacy. Imposing such requirement on all Ayurvedic and Unani products will certainly face immense push back especially from the Ayurvedic industry.

The Eighth chapter is The Dangers Posed by Traditional Medicine and Its Practitioners to Public Health which focuses on regulating the traditional medicine industry. It is clearly an uphill task but given the danger posed to public health, there is no other alternative. The Indian medicine practitioners prescribing modern medicine, there are simple solutions. Leaving it to the courts to sort out these issues is quite simply a terrible approach to governance.

The Ninth chapter is The Chaos of Indian Pharmacies and their Supply Chains emphasis on tackling issues of prescription abuse. The Ministry of Health must seriously consider using this opportunity to dramatically upgrade the current bare boned licensing requirements to open and run a pharmacy or engage in the whole -sale trading of drugs. The author ends the chapter stating that there could be no better time for the ministry of health to completely rethink the regulation of pharmacies in a manner that guarantees better storage of drugs during transit and distribution while protecting against prescription abuse and guaranteeing supply chain integrity.

The tenth chapter is Of Drug Advertisements, Promotions and Trademarks, wherein the chapter explains about Drugs Inquiry Committee under Col Ramanath Chopra 1931. Further, the author highlights on Drug and Magic Remedies (Objectionable Advertisements) Act which has been enforced against a range of advertisements for bewildering products. In 1975, the Supreme Court heard a case involving an advertisement in the Hindi newspaper *Sanmarg* in West Bengal, for a machine of science and electric treatment to treat amongst other conditions weakness, laziness, oldness in youth etc. The conviction and penalty of 100/- imposed by the lower courts was upheld by the Supreme Court. Similarly, the Madras High Court in 1990 refused to stay the investigation by the drug inspector. Wherein the case involved with advertisement in the Tamil weekly “Kalkanadu” for a Durka Ayurveda Tumbler, it was claimed that water drunk from tumbler was capable of controlling diabetes, blood pressure, weakness etc. Furthermore, the author ends that chapter stating that a more efficient system of regulation could be achieved by putting in place regulations that require all pharmaceutical companies to submit all advertisements, promotional literature and brand names to the national drug regulator for its permission before communicating the same to the general public. The drug regulator would need to create internal capacity to screen all such material thoroughly from a public health perspective.

The eleventh chapter is The Politics and Levers of Reforming India's Drug Regulatory Framework, the author states that the demands by the middle class for reform in India generally begin with the filing of public interest litigations before the supreme court. PILs are

a controversial procedural innovation by the Supreme Court which significantly dilutes the locus standi requirement, allowing persons to challenge government action despite not being directly affected by the same.

From above discussion it can be concluded that the effective reform can be achieved only when we educate people, especially doctors, who prescribe medicine. In the present book, an attempt has been made on law making process in the country.

Any reader, after going through the work of authors would have a thorough understanding of all the legal aspects pertaining to drug regulation in the Indian context. The authors have made tremendous contribution to the society by focusing on many unfortunate drug incidents. The book is useful to the law student, researcher, lawyer, teacher, judge, chemical engineer and policy makers. The book deserves to be in the library of every law school, advocate office, court and chamber of every judge, law teachers and scholars.

However, the overall analysis of the book chapters itself are not adequate in order to overcome from the practical problems. The author could have highlighted more on the role of doctors in medical negligence cases in addition to illegal pharmaceutical practices. Many Pharmaceutical companies do not check the composition in manufacturing drug which is major drawback in India. Further, authors have rightly pointed out by analyzing various judgments wherein it can be seen that the rate of acquittal is more than the severe punishment.

The authors have collected data from various government offices by filing application under RTI.Around 400 applications were filed under the RTI Act with the drug controllers and other government departments for collecting data across the country to expose the dark side of the government department. The author had filed petition before Delhi High Courtagainst the drug controller for releasing government order. Here point is that the gathering information from government official was quite challenging for the authors and at the same time it requires lot of patience. Hence the author makes the readers to rethink on Drug regulation law in practical perspective.

The book poses a salient question to legal scholars: to what extent do the Drug Regulation law matter for the development of a well-functioning of the country. Here authors make serious concern on health which is a fundamental right of every citizen of India as stated in Art.21 of the Indian Constitution. This book is a result of combining the works of chemical engineer and advocate which needs more appreciation from a practical point of view wherein we can observe how right to health has been violated during health emergency.

Overall, the chapters contained in this book complement each other and overlapping has been avoided. The authors mention about the role of judiciary to overcome the procedural bottlenecks. The legal instrument covered in the book is bound to reduce the burden of any researcher. The uniqueness of the book is that it addresses practical problems and provides valuable insight on how the regulation of drug has evolved along with other associated issues. The language used, illustrations, case laws given, authorities cited the systematic arrangements of chapters are a few of the strengths of this book.