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The Act That Wasn't by Dr Bobby George, Power Publisher 2017, pp 183

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Book Review

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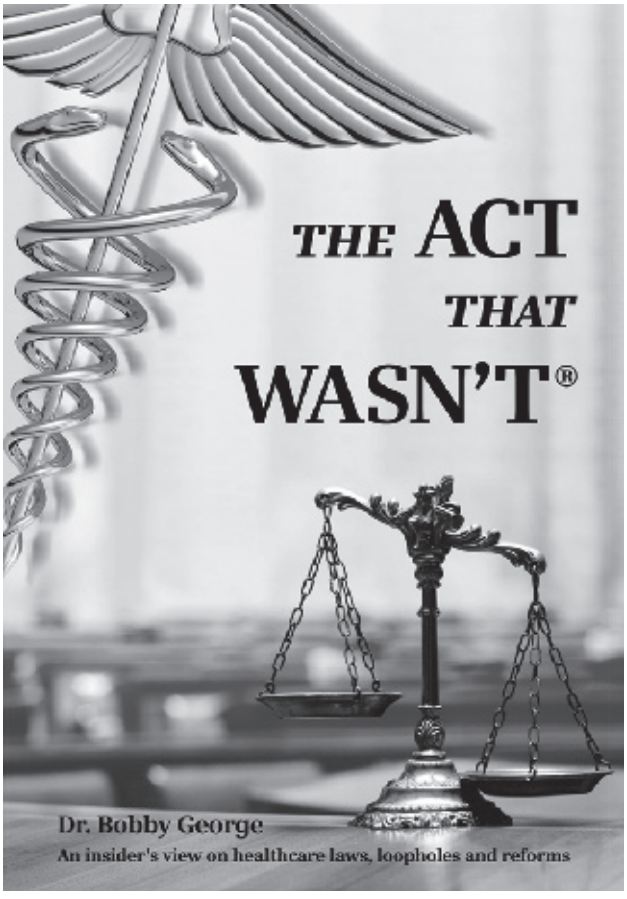
The Pharmaceutical industry is highly regulated all over the world. India is no exception (as a matter of fact it is over regulated and under implemented). India ranks third in the world in terms of volume and fourteenth in terms of value. Nearly 40% of the generic drugs manufactured by Indian Pharmaceutical companies are sold in the Western or developed markets of USA and Europe. We often read in the lay press that United States Food and Drug Administration (USFDA) bans certain formulations manufactured by Indian companies for lack of regulatory compliances. But for the recent ban of large number of Fixed Dose Combinations (FDCs), which is now stayed by the Honourable Courts, we do not hear such bans of substandard formulations in the Indian market by the Government. Is there a double standard in the quality of drugs consumed by Indian patients as against Western?

That brings us to the book, The Act That Wasn't, under review. The contents of the book cover wide range of issues in as many as 12 chapters. The book addresses issues ranging from "Acts and acts" to "Reformative acts". These chapters deal with how acts are enacted, repeal and replacement, dysfunctional, unhealthy, clinical study, organ transplant, surrogacy, bio similar and whistle blower protection act, etc. The range of titles of chapters is suggestive of the fact that regulating healthcare industry is very complex and the operative part is still more difficult. Unlike USFDA, in India the licensing agency for manufacturing of drugs is under the state Drugs Control and the policy making is by the Drugs Controller General of India (under Government of India). The author has tried to give the background of each "Act," compare it with such acts in other countries, and explain the pit falls and in many cases, give corrective measures. The contents are appropriately supported by references. Some of the measures suggested are reducing timelines for review, issuance of new rules and guidelines, strengthening existing standards and practices, digitalization drive besides others.



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The author, Dr Bobby George is a pharmaceutical scientist of long standing in the industry. He presently heads the regulatory affairs division in a leading company. The views and descriptions given are based on real experiences and are authentic. The writings are simple and straightforward. The contents are related to Government "Acts", an eminent former justice of the apex court of India has written the foreword to the book. The book is recommended as an informative text for teaching 'Forensic sciences/pharmacy' and also for libraries in pharmaceutical institutions and industry, and even for the libraries of Law colleges and Universities.