Review of *Bottle of Lies* by Katherine Eban for the Indian Journal of Medical Ethics (IJME)

In her book *Bottle of Lies: Ranbaxy and the Dark Side of Indian Pharma* author Katherine Eban, clearly and convincingly sets out a case against the corruption that has infiltrated the generic drug industry and Ranbaxy Ltd. in particular. The focus is on India though many of the same arguments probably could be used for China, another major producer of generic drugs. Some elements in India, including government and the generic drug industry have struck back, accusing the author of maligning Indian pharma and in the process, helping multinationals. Rather than “shoot the messenger” it might be best to address the issues that have been raised.

“Generic drugs are supposed to work as well as their brand-name counterparts. Once a patent lifts, generic-drug companies find alternative ways to manufacture a drug that should work indistinguishably from the brand-name version. As long as generic manufacturers prove their drugs were bioequivalent to brand-name drugs, i.e. they acted similarly in the body, they could get approved.” Less-expensive and effective generics have been providing low-cost care to millions.

The book documents many of the unethical practices of Ranbaxy including selling adulterated drugs, lying to the US Federal Drug Administration (FDA), destroying records, and fabricating others. The author also highlights questionable manufacturing practices. Many manufacturing facilities are located in hard to reach areas with few hotels, so inspectors are at the mercy of the people they are called on to inspect. Unannounced visits were easily controlled by the facility.

It would take years for the FDA to learn about the corruption and longer for action to be taken. Much of the initial information that triggered the investigations came from a whistleblower who was aware of many of the company’s irregularities. In 2013 Ranbaxy USA, pleaded guilty to several counts of selling adulterated drugs and lying to the FDA, paying over $500 million in fines and having restrictions placed on the importation of many of its products. None of the individuals responsible were prosecuted for these irregularities and many executives simply took their expertise to other generic-drug manufacturers.

Eban makes the important point that Cipla Ltd., the number one generic drug manufacturer in India, is an exemplary company that has been in the forefront of producing generic drugs for AIDS, for example, which has transformed treatment globally. She notes that the present director of Cipla, Dr Yusef K. Hamied and his predecessors have used Gandhian principles in developing the company and its ethical standards. “By contrast” notes Eban, “Ranbaxy grew out of a set of values diametrically opposed to Cipla’s.” The primary motivation was to make as much money as possible as quickly as possible. “Ranbaxy had no particular mission or vision.”

The US has become addicted to generics (90% of its drugs) as a way of keeping down health care costs for a health system with so many other unnecessary procedures and costs. Maybe that is why it took so long for them to respond to the charges. The FDA inspects production facilities in the US with visits that are often unannounced so as to maintain a level of vigalence among the manufacturers. Outside pressure from generic manufacturers, and the US Congress, however, has led the FDA to give foreign companies advance warning of inspections, allowing deception to grow and flourish. The US addiction to generics and that of others must be fed even if it comes at the cost of importing drugs of questionable potency and quality. While the inspection of facilities addresses issues of drug quality, misinformation or the non-reporting of negative findings, practices that have become all too common among large pharma are not affected. These issues are not addressed by Ebon.

Indian authorities and regulatory agencies should recognize that it’s not only others, especially the poor in India and Africa, who are affected by adulterated and low-quality drugs, but also the general public--friends, relatives, and themselves. Drugs made for the poor or destined for unregulated countries could just as easily slip into higher grade products. In Africa, where some manufacturers shipped their lowest-quality drugs, doctors would often prescribe much more than the typical dose so as to achieve the desired effect.

What then should India do? Firstly, regulation of companies manufacturing drugs should markedly improve as should drug testing. India should also consider instituting unannounced inspections with competent investigators. Maintaining high standards is not expensive relative to the cost of drugs and the cost of ineffective treatment. What about those who knowingly produce inferior products for local consumption or export? Penalties should fit the crime. If a person dies or is disabled from taking drugs that were purposefully adulterated or produced with no active ingredient, what punishment should be given to those who are responsible?