BOOK REVIEWS

Quality and corruption in the generic drug industry

RICHARD A CASH

Katherine Eban, *Bottle of lies: The inside story of the generic drug boom* (US edition), Harper Collins, 2019, pp 152, ISBN: 9780062338785, $28.50.

Katherine Eban, *Bottle of lies: Ranbaxy and the dark side of Indian pharma* (India edition), Juggernaut Books, 2019, pp 512, ISBN: 978-93-5345-044-1, INR 480 (hardcover)

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 "shooting 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" (1). 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 Food and 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.

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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, among the biggest generic drug manufacturers 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 chairperson of Cipla, Dr Yusuf K Hamied and his predecessor have followed 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 vigilance 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. As the US Congress controls the budget of the FDA which also receives substantial funds from the pharma industry, it is subject to external pressures.

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 Eban.

Indian authorities and regulatory agencies should recognise that it's not only the poor in India and Africa, who are affected by adulterated and low-quality drugs, but also the general public— themselves, their friends and relatives. 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? 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? Penalties should fit the crime, and those found guilty be held accountable beyond simply paying a fine, or having no punishment at all.

Reference

1. Lambert J. Book review: 'Bottle of lies' exposes the dark side of the generic-drug boom. *NPR.org.* 2019 May 12, updated May 14[cited 2020 Jan 21]. Available from: https://www.npr.org/sections/health-shots/2019/05/12/722216512/bottle-of-lies-exposes-the-dark-side-of-the-generic-drug-boom

Love in the dream drugstore

DAVID HEALY

Brian Earp, Julian Savulescu, *Love is the drug: The chemical future of our relationships*. Manchester University Press, 265 pages, £17.99, ISBN 9781526145413

It's difficult to resist a book with a title like this. You might expect it to mention Viagra and related drugs - nope. As far as chemicals go, this is an MDMA (Ecstasy) love-in, with a whiff of other psychedelics, and a smidgeon of oxytocin thrown in. MDMA here is not just a chemical - it's a trauma repair kit - helping foundering relationships by undoing trauma. We know this because MDMA has been used to treat PTSD, and if it helps relationships this must be what it's doing. This, and the linkage between oxytocin and bonding between mothers and infants, frames these chemical interventions as meaningful.

Building on a meaningful basis, precision-engineered chemicals are about to take us to an enhanced and progressive future. But before the Rapture, there are scenarios involving drugs to loosen attachments and reprogramme affections we should consider.

It's not clear how soon the authors think we will be transported into a new world. MDMA has been in regular use for half a century, and oxytocin has been billed as the relationship hormone for as long, without making any practical difference to our relationships so far.

It may be that a "cultural" template needed to change – that we needed to get comfortable with bio-hacking. Cognitive enhancers, were an entry point into this with many Americans taking "smart drugs" in industrial quantities but no appreciable difference to their intelligence levels (1). Smart drugs were an early tributary to what has become a Wellness flood, worth billions annually in the US, which might provide a shop-window for making relationships great again with relationship modifiers.

No mention in this book that in some Western countries the ability to make love has been wiped out for 20% of the population by SSRI (selective serotonin reuptake inhibitors) antidepressants. No mention that SSRIs can trigger an enduring sexual dysfunction after treatment stops, leading young people to commit suicide. No mention of the growing numbers of asexuals, born to mothers who were on SSRIs in pregnancy (2).

There are cautionary notes about anecdotes telling of good effects with drugs like MDMA and the need to wait for substantive clinical trial evidence:

> *The ethics of prescribing drugs off-label is tricky. Sometimes the evidence concerning appropriate doses, benefits, and risks has changed since the manufacturer's label was finalized. If you're prescribing a drug for the purpose it was originally intended for, in a way that is consistent with the best available evidence, and the evidence just happens to have changed since the label was printed, hardly anyone would seriously object (p 133).*

This is a road to a marketing of relationship modifiers aimed at fostering a permanent discontent that will lead to company profits rather than good relationships.

The authors also overlook the cabbage problem. Cabbages produce 47 different pesticides, many of which would not get on the market if attempts were made to license them, but they are what give cabbage its flavour (3).

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