

OPINION INDIA

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Delhi's Fake Drug Whitewash

The government's flawed research study endangers lives and crucial pharmaceutical investment.

By [ROGER BATE](#)

The proliferation of fake drugs is one of the greatest dangers facing India today. It threatens lives, discourages patients from using life-saving innovations and deters much-needed pharmaceutical investment. So it's more than a bit worrying to see the Indian government touting a new study that is little more than a whitewash of this crucial problem.

After literally months of leaks about the results, the "Report on Countrywide Survey For Spurious Drugs" was released by the Central Drugs Standard Control Organization in July. The report, conducted over a period of seven months last year, found that of 24,136 samples, 11 or 0.045%, were fake.

The CDSCO took pains to point out that their results flatly contradict reports over the past decade from scholars and industry groups claiming fake drug rates ranging from 3% to 35%. Indeed, the author expresses a clear aim to overcome the "apprehensions about the availability of safe and genuine medicines in India."



Little wonder: The Indian government is rightly proud of its pharmaceutical market, worth \$25 billion a year. Drug Controller General Surinder Singh claims that every second child vaccinated in the world uses a vaccine made in India, and that 45% of India's pharmaceutical production is exported to more than 200 countries.

But the report's results fail to pass even the most cursory of inspections. Not only are there discrepancies with international studies, but there are unexplained internal inconsistencies which undermine the findings. The report says, for instance, that its authors had no useful information about areas known for counterfeit drugs. This is inconceivable: New Delhi's Bhagirath Palace and certain markets in Agra and Aligarh are known to me, a foreigner, as major locations of the fake drugs trade.

More importantly, the report repeatedly claims that only three samples of 2,976 (0.101%) were found to be of substandard quality. The report is confusing because it says that only 305 samples were subject to chemical analysis (implying complex testing such as for impurities), which would indicate a failure rate of 1%—tenfold what the report touts. Yet later it implies that only basic active-ingredient analysis was done on all 2,976 samples.

At least 1% would be closer to reality than 0.1%. Previous assessments of many thousands of samples, undertaken annually by the government, show the number of drugs failing quality-control tests at about 10% in the 1990s and 7% in most of the years of the last decade. In an assessment of more than 700 samples in 2008 and early 2009 in three Indian cities, my research team found about 8% failing tests (58 samples failed out of 720), which broadly concurs with the government's far larger samplings.

It's reasonable to assume the report generated untrustworthy findings because the samples were biased. Vijay Karan, a former Delhi police chief, told me that many pharmacists are routinely aware of when and by whom government surveys would be done. The report itself notes retail pharmacists in cities "refused to sale. . . the schedule drug without prescription." But of the 70 or more pharmacies in cities we visited in our studies at the American Enterprise Institute, none demanded prescriptions. Either pharmacists voluntarily and drastically changed policy in the past year—or they were alerted to who the covert buyers really were and reacted by following the letter of the law, not their usual practice.

Conducting covert surveys requires following a careful protocol. In our peer-reviewed studies for the Public Library of Science One Journal, we were grilled by reviewers about how interviews were conducted, since poor sampling might have biased the results. Yet the CDSCO report includes only a single sentence on the importance of sampling protocols. Nowhere in the report is the drug-collection protocol actually discussed.

On a more minor level, the report also contains telling typographical and reporting errors, such as in the first table, where samples are referred to as "Not of Sub-Standard Quality," when the author means "Not of Standard Quality."

In the final analysis, the CDSCO report is a well-conducted analysis of probably dubious data, which makes the results useless. If this were a minor report, that might be a passable error. But given the life-threatening nature of fake drugs, it's not something the government should tolerate. A Pew poll last month found that 54% of Americans distrust drugs made in India. No wonder.

Mr. Bate is the Legatum Fellow at the American Enterprise Institute.