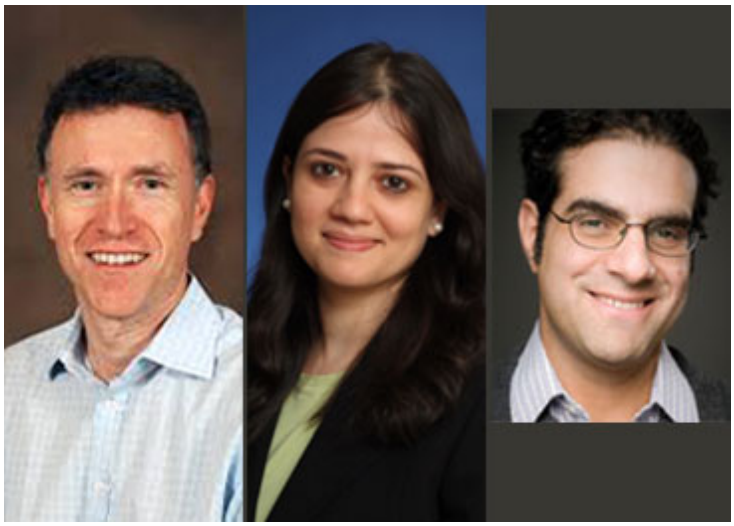
BioSpectrum the business of Bio & Health Sciences

US think-tank dares Indian government on legal action

19 October 2014 | Features

US think-tank dares Indian government on legal action



The paper triggered severe reactions from the Indian government, pharmaceutical fraternity and industry bodies to the point of legal action against AEI.

"The samples were collected between 2009 and 2012. But the paper does not clarify as to when and where were they tested and why did it take two years to write the report, asks Mr D G Shah, secretary general, Indian Pharmaceutical Alliance (IPA), when contacted by *BioSpectrum*.

The publication has been authored by 4 PhD scholars namely Prof. Amir Attaran, faculty of law, Institute of Population Health, University of Ottawa, Canada; Dr Aparna Mathur and Dr Roger Bate, scholars, American Enterprise Institute; and Prof. Ginger Jin, Department of Economics, University of Maryland.

According to the paper, Legatum Institute has funded the collection and testing of all the medicines. The study also recognizes that transportation and storage conditions could have impacted the quality of products tested.

Coincidentally, the paper was released during Indian Prime Minister Narendra Modi's US visit. "The timing of this publication and the planned publicity in the media suggests that it was not a coincidence," justifies Mr Shah.

On the other hand, Dr Aparna Mathur told *BioSpectrum* that the research paper is an academic paper on drug quality. "We had no political reason to write it, nor are we trying to defame Indian manufacturers. We report problems with some of the drug samples that we find, and we urge governments to crack down on poor quality drugs. It is beyond our understanding why the government would attack us for writing this paper instead of trying to go after the people who made the bad drugs."

The authors said that around 1,470 samples of antibiotics and tuberculosis (TB) medicines claiming to be 'Made in India'

were examined. "The samples were collected from five cities inside India as well as 17 low-to-middle-income countries outside of India, and tested for quality using the Minilab protocol," the authors quote.

The examination led the researchers to conclude by saying that 10.9 percent of the tested products failed the basic assessment of active pharmaceutical ingredients (API). "And the majority of the failures are substandard (7 percent) as they contain some correct API but the amount of API is under-dosed," the paper reported.

If the researchers' real concern were quality of drugs, they could have approached the drug regulatory authorities in India and the importing countries with full details of products, manufacturers, test methods and results, added Mr Shah.

"However, apparently, that is not the intention. Instead, they have approached the media first to malign the country and its industry," he said.

In another place, the scholars claim that most of these Indian-made drugs were of poorer quality when purchased from Africa than from India, or from Non-African mid-income countries such as China, Brazil, Turkey, Thailand, and Russia.

In the paper, the authors have not revealed the names of the manufacturers owing to guideline commitments.

"Instead of disclosing the names of products and their manufacturers which were allegedly found to be substandard, the study tarnishes the whole Indian pharmaceutical industry. This is unfair to the companies that ensure quality standards and to the country which has come to known as 'pharmacy of the world'. The government is therefore considering appropriate legal action," expressed Mr Shah.

Earlier this year the USFDA discredited one such research study by the same researchers which claimed *'Impurities in Dozens of Generic Heart Drugs Made Overseas'*.

Mr Shah backed it up by saying, "The USFDA observed that the investigators themselves had contaminated the samples during their testing." The study was undertaken by Dr Preston Mason, a researcher at the Harvard-affiliated Brigham and Women's Hospital in Boston, USA. It was presented by Dr Mason at a congressional briefing in February 2014.

When AEI witnessed intense reactions from India, it published an article as a counter-argument dated October 15, 2014, titled, '*India's Misguided Response to our Findings on the Quality of Drug Exports'*.

The authors counter-argue saying, "It is quite common for academics to publish studies that governments dislike, but not common for governments to sue them for it. However, as a recent paper in Foreign Policy noted, the Bharatiya Janata Party (BJP) and the Modi government have a nasty habit of suing and criminally prosecuting their opponents."

To a query by *BioSpectrum*, one of the authors, Prof. Amir Attaran responded saying, "For my part, I can say that I have no fear at meeting India's government in court, if the Indian government is so foolish as to go there. Not even dictatorships such as Russia or North Korea are crazy enough to sue university academics for the research, but the available evidence is that India's government and pharma industry wish to be that intolerant and extremist."

Mr Shah feels that this report is unlikely to tarnish the Indian drug industry. "Drug regulators in the mature markets and emerging markets have greater confidence in the capability of their organizations to ensure compliance with their standards. They would rather believe their own staff than this so called 'academic research', which is neither academic nor research," he opined.

Prof. Attaran concluded by stating, "Little could do more to drive home the backwardness of India's drug regulatory institutions, and incestuous nature of the relationship between India's pharmaceutical industry and the government, than such an ill-liberal and ill-considered bit of litigation. Just the threat that has been made should embarrass Indian citizens profoundly. So my message to India's government is this: 'Bring it on if you dare'."