



Four dollar generic medications, how safe are they?

To the Editor:

The American people are becoming aware that many pharmacies have recently begun offering generic medications for only \$4 for a one-month supply and \$9 for a three-month supply. Although this is a very commendable and fiscally responsible act to benefit consumers, consumers could ultimately pay for it with their health if the FDA does not remain vigilant.

Most generic medications today are manufactured in Europe, India, or Israel and have regular and rigorous inspections of their manufacturing process by the FDA. These manufacturers have a long history of providing safe, effective, and reliable medications to consumers in the United States. The FDA requires generic drugs to be within the specified range of 80% to 120% effective as the brand-name medication they are replacing. The generic drug manufacturers in Europe, India, and Israel have a proven track record of meeting those parameters set by the FDA and have always passed the rigorous inspections by the FDA for many years. The new player in the game is now China, and they are providing the generic medications to many pharmacies for their generic prescription plan and I hope they are subject to the same rigorous inspections by the FDA. Many, if not most, consumers are aware that in the past, China has had many problems with many of their manufacturing industries, including but not limited to infant formula,¹ dog food,² lead paint on toys,³ and even generic drugs including heparin.⁴ I am not suggesting that China is not capable of manufacturing a high standard of products, but the aforementioned examples do raise the question about the safety of the generic drugs manufactured in China, and we need an assurance by our FDA in this regard. In my opinion, for the safety of American consumers, the Chinese manufacturers of generic drugs must comply with the FDA's mandated inspections, and the FDA should assure us that this is being done. For consumers and health care providers, it is virtually impossible to know whether a medication is of poor quality or contaminated, until a tragedy happens. Roger Williams, chief executive of the US Pharmacopeia, was quoted in 2007 saying, "We should be

concerned, because the US safety nets are frayed, and China has become a poster child for problems."⁵ I hope that the Chinese government has put safeguards in to prevent recurrence of an example in 2008 when heparin made from ingredients imported from China was linked to hundreds of serious adverse reactions, and included as many as 81 deaths in the United States.⁶

I have not been able to find whether the FDA has any contacts, jurisdiction, or other useful liaison with the Chinese generic drug manufacturers. We need the FDA to reassure us that they have some jurisdiction and/or monitoring system in place, and that past problems with drug manufacturing have been adequately addressed in not only China but all of the other countries that supply us generic drugs.

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