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Faking It

Drug counterfeiting has become a major problem for the FDA today; a variety of solutions is needed



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Once, when I was at the Department of Health and Human Services in Washington, a top pharmaceutical official produced two boxes of his company's pills and asked me which one was counterfeit. Seeing no difference, I said I could not tell which one was fake. He replied, solemnly, "Neither can we."

This brief story illustrates an enormous problem facing the FDA and the US medical products market: counterfeits. Counterfeit drugs have always been something of a problem in the US: there are always criminals drawn to any lucrative market. However, some aspects of this problem are new and disturbing. Globalization plays a role. With so many active pharmaceutical ingredients (APIs) and excipients being sourced outside of the US, the possibility has grown that foreign counterfeiters can assemble drugs and penetrate the US market.

The problem is no longer just lookalike drugs, in which the unwary purchaser gets what is essentially a placebo. Instead, the counterfeiters now have access to APIs and can make the drug itself. Unfortunately for consumers, they also sometimes don't have the drug recipe, and adding more API to a drug is not a benefit to the consumer, but a potential health hazard.

Counterfeiting is not only a health hazard; it strikes at the very basis of drug regulation in the US. If the US government cannot stop counterfeit drugs from entering the US, and thereby protect consumers from the counterfeiters, the FDA's regulatory regime imposes costs on compliant drug companies without providing adequate protection for consumers. Counterfeiting also strikes at the economic basis of the medical products industry, which must make up both lost sales as well as the routine expenditures of research and development in their own, legitimate sales.

The FDA inspects an admittedly small percentage of imports into the US. With inadequate resources, the FDA has increasingly turned to computer-based analy-

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sis and other means to cover the disparity between the quickly growing number of imports and the not-so-quickly growing resources of FDA inspectors.

In recent years, furthermore, counterfeiters have become ever bolder. Earlier this year, the FDA cracked down on websites that advertised therapies for the H1N1 virus that were not FDA approved. Websites and e-mail spammers alike promise inexpensive drugs to unwary consumers. Although public education has to play a role in this area, the FDA also is going to have to work to reduce fly-by-night operations that target vulnerable consumers. If the FDA continues to focus on going after the legitimate pharmaceutical industry for lucrative off-label marketing settlements, it will not have enough resources and personnel to deal with predators who reach out to everyone with an e-mail account and whose existence casts doubt on whether the FDA is fulfilling its most basic public health mission of preventing bad products from reaching consumers.

Besides providing more resources to the FDA's strained personnel, another solution is to allow broad third-party certification of manufacturers, and create a cadre of trusted non-governmental inspectors to spread the burden of inspection and verification. A final piece of the solution will come from harmonizing of regulatory regimes to close the gap in expectations between the US and its major trading partners. It is heartening to note the outreach to China, India, and Brazil in these areas, but much more remains to be done. ♦

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