With as many as 14,000 people exposed to tainted steroid injections, resulting in more than 200 infections and 15 deaths, and more expected in the coming weeks, the drug delivery system is once again coming under scrutiny and has been threatened with loss of confidence.

In the shameful steroid contamination scandal now continuing to evolve, the New England Compounding Center appears to have exploited an astonishing loophole. Compounding pharmacies are supposed to mix custom combinations of drugs from already manufactured materials when ordered by a doctor. Some compounding pharmacies will pre-mix certain recipes. They call it "anticipatory compounding." In the case of the fungus-tainted steroid, the New England Compounding Center mixed a batch of 17,000 doses. Massachusetts Gov. Deval Patrick has said that the company was operating outside the limits of its state license.

"What they were doing instead is making big batches and selling them out of state as a manufacturer would," Patrick said Wednesday at a news conference.

Every few years a major scandal revolving around patient safety brings us closer to a profound question: How can this continue to happen?

Some of the past headline pharmaceutical failures have resulted from negligence, lack of oversight or self-recognized problems. Other problems, like the current steroid tragedy and the distribution of phony heparin just a...
few years ago are caused by rogues.

Every industry has its offenders and rogues. The world of asset management had Bernie Madoff; Washington lobbyists and political advisors had Jack Abramoff; and football coach Jerry Sandusky is now deservedly serving 30 to 60 years in prison. Yet, even the most stringent oversight can't identify every potential problem and no government can post police at every corner to assure that rules and laws are obeyed.

Drug development and delivery is a long and tortuous process. It starts in a laboratory, where basic scientific knowledge is enhanced and ends when a pharmacist fills a prescription or a patient takes an over-the-counter medication off the drug store shelf.

Science that results in a new drug advances in steps. Building scientific knowledge is like building a brick wall. If the bricklayer has to personally inspect every brick before placing it in the wall, progress is delayed. If the bricklayer assumes all the bricks are solid but some are not, the wall could be seriously weakened or even collapse. In the pharmaceutical world, each brick in the process of developing and delivering a drug must be reliable or people's health, and potentially their lives, are in danger.

The painful reality is that there are many gaps in the reliability and accuracy of the drug development chain. Not only is the end of the chain sometimes tainted, but increasingly, so is the beginning.

**Meningitis Outbreak: Restoring Confidence in Drug Industry**

Peer-reviewed publications are the standard of excellence in the scientific world. They are the reliable source of progress for each of the disciplines they represent. When peer-reviewed publications publish and then retract a report, it is because something in that report was inaccurate. In a recent issue of the prestigious journal Proceedings of the National Academy of Sciences, the authors reported that there has been a 10-fold increase in retracted scientific papers since 1975.

The authors, who reviewed more than 2,000 reports, concluded that 67.4 percent of the retractions were due to misconduct, including fraud, suspected fraud, duplicate publications and plagiarism. Only 21.3 percent were attributable to error.

Some people believe that this precipitous rise in retractions is caused by sloppy work in a competitive publish-or-perish environment, or that the rate of errors is the same as it always was, but that detection is more frequent because of increased sophistication of computer systems that detect errors. But computer searches that can detect errors after publication should also be able to detect errors before publication.

Not long ago, you could trust that information in a scientific journal or presentation was truthful. Scientists may have made mistakes in procedure or evaluation, but you could believe they were telling the truth as they understood it. Increasingly, this is not so today. The Department of Health and Human Services' Office of Research Integrity Division of Investigative Oversight reports that it handles approximately 200 allegations of research misconduct each year.
Not that long ago, you could walk into a drug store and be pretty certain that the non-prescription drug you took from the shelf or the prescription drug you received from the pharmacist was pure. Increasingly, this is not so today.

We are now facing questions of integrity and failure of self-regulation, which are the underpinnings of scientific credibility. In previous eras, the scientific community was relatively small and concentrated in Western Europe and the United States. Scientists in a particular field knew one another and read each other’s reports. Peer pressure kept most honest and accurate. Data was shared among researchers. Scientists would repeat experiments to verify the accuracy of each other’s results. Peer-reviewed publications would make information available to all in a field and government regulation could catch mistakes before they affected the general public.

Science has always been competitive and it is becoming more so. Today, academic researchers are increasingly competing for scarcer government grants. Industrial scientists and corporate laboratories are being put under tremendous pressure because of continuing cost-cutting initiatives and increasing demands for productivity. The scientific community has become huge, spanning countries that were never before centers of scientific advancement, and the pace of scientific progress has made it impossible to track all advances in a discipline, even in some that are highly specialized.

In a competitive world, where pursuit of patent protection is king, scientists are loath to share data. Peer-reviewed publications have failed to detect fraud and mistakes, while rogue companies and sometimes established name-brand enterprises escape government oversight through loopholes in regulation or the inability of the government regulators to be everywhere.

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Though the systems for insuring the credibility of scientific reports and the safety of the drugs we take work most of the time, most is not enough when lives are at stake. There will always be loopholes and regulators will never be able to spot unsafe situations before problems arise. Large fines and factory closings only stop bad drugs from reaching the public after the damage has done. For some companies, billion dollar fines could well become just another cost of doing business that is passed along to customers and shareowners.

The step mentioned in the title may be opening the door to a new era of transparency. GlaxoSmithKline, a large international pharmaceutical company, is taking a radical approach to delivering safe and reliable drugs. After Glaxo was fined $3 billion for misbranding a drug to treat depression in patients under 18 and withholding safety information about a diabetes medicine, the company said it learned from its mistakes.

Last week, Glaxo CEO Sir Andrew Witty outlined new measures for the company to more openly share its intellectual property and knowledge, and to help stimulate R&D into diseases that most affect the world’s poorest people. The company will make clinical research data that is often closely held, available for review by qualified researchers once a drug has completed the approval process or has been abandoned.

Witty committed to releasing information about 200 of Glaxo’s experimental drug compounds that have shown signs of fighting
tuberculosis, a huge global health threat for which progress has been stymied. He also pledged that the company will support independent research into other diseases of the developing world.

Glaxo’s announcement was a good first step. It may not provide for total transparency, but in an era when billion dollar blockbuster drugs are losing exclusivity, when pharmaceutical competition has never been greater and large drug companies are downsizing to cut costs and maintain margins, Glaxo’s initiative is counter-intuitive. Yet it is beneficial for the company as well as its customers.

Glaxo has the potential to take that all-important first step in maintaining confidence in a system that cannot exist without it. Hopefully, by setting an example for the rest of the research and pharmaceutical business, other developers and manufacturers will follow, thereby reducing the need for and cost of government regulation, which is paid for by customers, shareowners and taxpayers.

Steve Brozak is president of WBB Securities, an independent broker-dealer and investment bank specializing in biotechnology, medical devices and pharmaceutical research. Henry Bassman is a managing director at WBB Securities.

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