IPEC's Push for Third-party Auditing of Excipients

Jim Wiltraut

Director of Federal Government Relations
Buchanan Ingersoll & Rooney PC

Robert Pinco

Buchanan Ingersoll & Rooney PC

Just like everything else in our homes, more and more of the products found in our medicine cabinets are being produced outside of the United States and, in some cases; pharmaceutical products made in America have ingredients made in other countries. Increased overseas production of pharmaceutical goods is the current trend for both drugs and their components, and as such production increases, the need for stricter oversight grows more urgent.

The pharmaceutical industry has long known what Washington is just now coming to realize; while eager to do something about the problem, the Food and Drug Administration (FDA) lacks the resources to provide sufficient oversight and with some in Congress, perhaps in frustration, looking to "de-fund" portions of the agency, the FDA's ability to effectively protect the pharmaceutical supply chain won't improve any time soon.

At a recent gathering on July 12, 2011, the PEW Health Group presented a report titled "After Heparin: Protecting Consumers from the Risk of Substandard and Counterfeit Drugs." Recognizing that so much of what goes into our drug products is made off-shore, the report called for the FDA to be given more power to protect the supply of drugs and drug ingredients. During the presentation, even Deborah Autor, newly appointed Deputy Commissioner for Global Regulatory Operations and Policy at the FDA, recognized that the agency could only do so much under current law.

IPEC (the International Pharmaceutical Excipients Council) has been working with Members of Congress and their staff on a legislative proposal which would empower the FDA by establishing a more formalized third-party auditing structure to protect the pharmaceutical supply chain from the infiltration of economically-motivated adulterated excipients.

Dale Carter, Chairman of IPEC, and a dedicated cadre of industry leaders who make up the group's executive committee, continue to storm Capitol Hill with a legislative initiative that would direct the FDA to recognize accredited third-party auditors to certify that manufacturers, distributors and importers of excipients meet safety standards which are in compliance with the Federal Food, Drug, and Cosmetic Act (FFDCA). The initiative would also call for the establishment of qualification standards for third-party auditors

and certifiers who have the necessary expertise and training in auditing techniques.

To give real teeth to the FDA, IPEC's proposal would mandate that individuals or companies not be allowed to import into the United States, a drug or excipient used in the manufacture of a drug, if the product or ingredient was manufactured or produced outside of the United States by an entity which has not been certified by the FDA or by an FDA- recognized third party auditor.

In short, the proposal would provide the same powers to FDA that Congress provided the agency as it relates to contaminated food, but that it still lacks for drugs…the power to keep contaminated or adulterated products or ingredients from reaching the pharmaceutical production process.

The idea of third-party auditing, and overall industry engagement in the effort to secure our pharmaceutical supply chain is really nothing new. IPEC has been around for 20 years, and since its inception has been actively engaged in raising the profile of excipients and the need for greater regulation of their production.

IPEC came to the realization that even FDA had not focused real attention on excipients, and the organization quickly realized that self-regulation and the establishment of stringent standards was the best course of action. In the 1990s IPEC created Safety Guidelines which were eventually included by FDA in its Guidance: "Non Clinical Standards for the Evaluation of Pharmaceutical Excipients." These Guidelines are still being used today by FDA and the industry for developing new excipients. IPEC, with FDA's input more recently also created a "Novel Excipient Review Process" to intelligently evaluate the safety of such ingredients.

About ten years ago, IPEC expanded its efforts into voluntary auditing of excipients to ensure that quality excipients were imported into the global supply chain. As the pharmaceutical industry has become more globalized, the opportunity for what FDA terms Economically Motivated Adulteration (EMA) has become a critical issue.

IPEC also launched a multi-year effort to create Globally Harmonized Excipient Pharmacopeial Monographs and create current Good Manufacturing Practices (GMP) Guidelines. Over the history of the group, IPEC has continued to refine ways to self-regulate and when crises occurred, as with the Mad Cow Disease impact on gelatin, they helped coordinate a cross industry effort to support FDA and the U. S. Department of Agriculture (USDA).

IPEC is now a Global Federation of over 300 companies, and the group continues to work closely with government regulators in various regions of the world, such as FDA and their counterparts in Europe, Japan, (and more recently in China, Brazil, and Argentina). The purpose was, and is, to find ways to protect patient safety and assure that quality excipients are incorporated into pharmaceutical products.

IPEC is a trade association of the "willing." Members around the globe try to produce and formulate safe and effective pharmaceuticals, but until FDA and their regulatory counterparts around the world have the tools necessary to inspect facilities, confiscate materials and cooperate on a system of third-party auditors to help in the process, adulterated and counterfeit pharmaceuticals will continue to threaten the safety of our global pharmaceutical supply chain.

Author Biographies

***Mr. James Wiltraut**, Director of Federal Government Relations at Buchanan Ingersoll & Rooney is best known in Washington for representing clients in the areas of national defense and homeland security. Jim also has extensive experience representing pharmaceutical companies, as well as energy companies, including those involved in the trading of biofuels, oil, gas, coal and other commodities. Jim helps Fortune 100 companies and small start-ups navigate the complex web of state and federal agencies and facilitates the building of new partnerships with local, state and federal governments in order to better link companies to the communities in which they operate.*

***Robert G. Pinco** reprsents worldwide brand-name pharmaceutical and chemical companies, as well as prominent technology companies. Robert's practice involves conformance with manufacturing, distribution, labeling and advertising requirements for a wide variety of drugs, medical devices and biotech products, cosmetics and basic chemical, both nationally and internationally.*

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