

# House Committee on Ways and Means

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Testimony Before the Subcommittee on Trade  
of the House Committee on Ways and Means

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On behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA), I thank Chairman Levin and the Subcommittee members for organizing today's hearing on intellectual property rights enforcement in China. Intellectual property rights drive innovation in the bio-pharmaceutical industry and enable the development of new and improved medicines for patients. PhRMA strives to uphold and defend these rights around the world. China is no exception.

My testimony will focus on the top three IP concerns for our industry in China: Specifically, pharmaceutical counterfeiting, protection of clinical data and patent reform. We estimate that the economic damage resulting from poor IP enforcement costs the industry approximately 3.4 billion dollars in lost sales annually. This is, in fact, a conservative estimate because it only captures quantifiable losses due to the lack of patent protection and data exclusivity for many products. It is impossible to know what percentage of the legitimate pharmaceutical market in China is supplied by counterfeits.

## Pharmaceutical Counterfeiting

While the Chinese Government has undertaken a series of actions to combat drug counterfeiting, the prevalence of counterfeit drugs within and originating from China nevertheless remains a substantial concern. Indeed, China is believed to be the world's leading exporter of counterfeit drugs and bulk chemicals.

Although pharmaceutical counterfeiting is subject to criminal, administrative and civil remedies under China's trademark laws, the effectiveness of such remedies is undermined by burdensome evidentiary requirements and weak enforcement. Anti-counterfeiting efforts are hindered by the general reluctance of administrative authorities to impose deterrent penalties and transfer cases to criminal authorities. Moreover, border enforcement is undermined by excessive bond requirements, a lack of transparency and short filing deadlines.

Significant weaknesses in China's drug safety regime contribute to the proliferation of counterfeit pharmaceuticals in China and the global export of inherently dangerous products. Pharmaceutical counterfeiting is first and foremost a drug safety violation. Thus, the adequacy of China's response to pharmaceutical counterfeiting must be measured against the framework of laws that regulate the various links in the drug manufacturing and supply chain. In that regard, China has yet to enact laws that address all aspects of drug counterfeiting activity or to provide the kind of enforcement resources and commitment necessary to combat this growing problem. For example, although China's drug laws prohibit "fake" medicines, criminal liability is conditioned upon proof of harm, a statutory requirement that, in practice, requires evidence of a serious defect in quality. This burdensome and excessive evidentiary requirement all but precludes criminal prosecution against counterfeiters under China's drug laws.

Another significant deficiency is the fact that China's drug regulatory authorities lack sufficient investigative powers and resources to take effective action against upstream manufacturers and suppliers. As a result, regulators are forced to rely upon criminal authorities to target counterfeiters; as noted above, however, criminal authorities are hamstrung by excessive evidentiary requirements. The net effect is a system of drug safety laws that provide no meaningful deterrence against the manufacture and distribution of counterfeit pharmaceuticals. Moreover, once counterfeit drugs reach the border, there are virtually no checks in place to prevent their export to other markets.

To rectify these problems, it is imperative that China amend its drug laws to prohibit and criminalize the manufacture, distribution, import or export of any pharmaceutical that is deliberately mislabeled as to source or identity (consistent with the WHO definition of a counterfeit medicine), without the need to prove harmful effects or deficient quality. In addition, China should create an interagency, pharmaceutical task force of law enforcers, regulatory authorities and customs agents to ensure adequate coordination among the various authorities with relevant oversight and enforcement responsibilities.

Each of these officials must be given the investigative powers and mandate to prosecute all links in the counterfeit drug chain, including manufacturers, wholesale and retail distributors and exporters of counterfeit medicines and related packaging and raw materials.

An important factor contributing to the pervasiveness of drug counterfeiting is that Chinese chemical manufacturers are producing bulk active pharmaceutical ingredients (API) which are being used in the manufacture of counterfeit drugs.

China has thousands of chemical companies, and there is evidence that some are producing and selling API in bulk form to downstream counterfeiters, often via the internet. The downstream manufacturers further process the chemicals into counterfeit pills and tablets sold within and outside of China, including the United States. Unfortunately, under current Chinese law, the chemical suppliers who are conducting such activities are not operating illegally under Chinese law.

According to Chinese Drug Administration Law, a chemical company is subject to government oversight by the SFDA when it "chooses" to register a specific API product with SFDA. It is only when the chemical company declares that it is making an API to be used in a finished pharmaceutical good and after the SFDA grants a product registration number that the company is legally permitted to supply API for inclusion in a finished pharmaceutical product. Under the current regulatory framework, if a chemical company manufactures an API, but elects not to declare that the API will be used in a finished pharmaceutical good, there is no government agency that possesses authority to preclude this activity from occurring.

The SFDA recognizes the importance of patient health and safety by regulating chemicals that will be used in finished pharmaceuticals. However, clear evidence exists that chemical companies are ignoring SFDA requirements by advertising their API products on commercial websites in the bulk form under the category of "(for) medicinal use" while not adhering to SFDA GMP regulations. Chemical manufacturers are freely selling and shipping API products to locations within China and abroad with either no regard for the intended use of the API or flagrantly choosing not to comply with existing Chinese regulations that would bring them under the oversight of the SFDA. These unregulated and unethical practices by chemical companies contribute significantly to, and, in some cases, aid and abet the counterfeit drug trade.<sup>[1]</sup> More troubling is that the unregulated distribution of API exposes patients to serious and significant health risks as well as degrades consumer confidence in the global medicinal supply chain.

Addressing the Most Prevalently Counterfeited Medicines

PhRMA recommends that the SFDA impose special requirements on the API substances of the 10 most commonly counterfeited pharmaceutical products in China (the “Listed API Product(s)”) according to the data compiled and updated jointly by SFDA and the Ministry of Public Security on an annual basis. SFDA could require all chemical companies manufacturing one or more of the Listed API Products to comply with all SFDA Good Manufacturing Practices (GMP) requirements, as if it were to be used in a legitimate finished pharmaceutical good.<sup>[2]</sup> Additionally, SFDA could require that the chemical companies certify that they will maintain detailed records of the recipients of each shipment, the quantity, the intended use of the Listed API Product being shipped and the Business License showing the business scope of the recipient. These records could be made available to SFDA officials should they ask to review the records. If the chemical company fails to maintain appropriate GMP, provides a false certification and/or fails to keep accurate records, the SFDA should have the authority to impose deterrent penalties, including a fine and a notice of its violation to the local Administration of Industry and Commerce (AIC) to whom the chemical company is registered and the possible revocation of the company’s operating license should multiple violations occur.

PhRMA supports the formation of a working group between industry, SFDA, the Ministry of Commerce and the Ministry of Public Security to address the problem of counterfeit API and to discuss the proposal outlined above.

### Clinical Data Protection

Following accession to the World Trade Organization in 2001, China revised its laws to incorporate concepts from Article 39.3 of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Article 39.3 provides that a country must protect data submitted in the context of a drug registration application from unfair commercial use. Loopholes in China’s current regulatory environment allow for unfair commercial use of safety and efficacy data generated by PhRMA member companies.

One such loophole exists because China defines “new drug” as any drug not previously marketed in China. Chinese domestic companies can file a “new drug application” for approval of a compound if that compound was previously approved by a regulatory agency in another country. Although the SFDA requires some limited clinical data on local populations for drug marketing approval, it relies heavily on published material generated by originator companies in the country of first launch. The published data, however, is insufficient by itself to prove the safety and efficacy of the product. But for the full clinical dossier that was submitted to the FDA in the U.S. or EMEA in Europe, China would not grant marketing approval on the basis of the limited clinical data required for regulatory approval. This is evident from the fact that China distinguishes products that have never received marketing approval anywhere in the world from those that are simply “new to China.” Products that have never been approved anywhere in the world require considerably more safety and efficacy data than products that have received prior marketing approval.

PhRMA views China’s deference to published material and regulatory decisions by agencies outside of China as reliance on clinical data developed by originator companies. The published data alone are usually insufficient to prove the safety and efficacy of a product. The published data merely summarize the data included in the original filing. The original data were necessary to demonstrate the safety and efficacy of the product. Reliance on summary data or approvals in countries outside of China conveys an unfair commercial advantage to non-originator companies because non-originator companies do not incur the cost of generating their own clinical data.

In practice, the SFDA receives numerous applications for marketing approval of a compound once it is approved in the United States or Europe. The originator’s application may or may not be the first

application SFDA receives. SFDA has interpreted the data protection provision of the Drug Registration Regulation to apply after marketing authorization is granted in China. Marketing authorization can take up to four years. During this period additional applications from Chinese companies can be submitted to the SFDA. Any company that receives authorization to begin limited, local clinical trials before marketing approval is granted to the first company is permitted to complete the regulatory process. This can result in multiple companies entering the market with the same product – and no effective data exclusivity for the originator.

In the United States, any non-originator company can seek regulatory approval during the data protection period if it submits a full data package consistent with requirements of a New Drug Application (NDA). China, however, grants marketing approval for products based on incomplete data filings. Applications in the United States during the data exclusivity period must include all elements of the NDA. An abbreviated application is not accepted during the data exclusivity period.

For the above mentioned reasons, we encourage China to revise its regulations to close the loopholes that permit the unfair commercial use of clinical data generated at considerable cost and risk by US companies.

### Patent Reform

We encourage China to “link” its patent system and the regulatory approval system. Such linkage would ensure that the SFDA does not grant marketing approval to third parties without authorization of the patent owner if the products are still covered by a patent. Linking the patent system and the regulatory approval system will not only facilitate effective enforcement of pharmaceutical patents, but will avoid the need for infringement actions in these types of cases.

### Conclusion

In conclusion let me stress that we are committed to the China market and to Chinese patients. We want to work with the Chinese Government to resolve problems in a collaborative fashion and welcome the U.S. Government’s support of these initiatives. I have limited my remarks today to the industry’s IP concerns in China. I have not touched on the very substantial market access barriers the industry faces. China is a dynamic and complex market that warrants the attention of this Committee and the Administration. We look forward to working with you to foster a better business environment for American companies operating in China. The U.S. pharmaceutical industry houses some of the best scientific minds in the world and is the global leader in biomedical innovation. With respect to innovation, the goals of this industry are consistent with the goals of this Congress: To quote House Speaker Nancy Pelosi, we share “*a steadfast commitment to being the most competitive and innovative nation in the world.*” China seeks to become a world leader in many innovative industries. Allowing them to steal the intellectual property of U.S. companies only encourages the shift of high paying, high skilled jobs in the pharmaceutical industry from the U.S. to China. We seek your support in upholding intellectual property protection around the globe and here at home to sustain the innovative nature of our industry – and to ensure that new and improved medicines are available in the future.

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[1] Under U.S. law, a supplier of active ingredient for a drug that will be marketed in violation of the Federal Food, Drug, and Cosmetic Act (FDCA) may, if the supplier is knowingly involved in the illegal activity, be charged with a conspiracy to commit that offense, 18 U.S.C. 371. In addition, the supplier who knowingly helps its customers in violating the counterfeit prohibition could be charged for aiding and abetting a violation of a U.S. federal statute, 18 U.S.C. 2.

[2] Active Pharmaceutical Ingredient (API), for this purpose, should include those components and intermediates of the product that may undergo chemical change during the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect.