

## Rare Criminal Prosecution Highlights Sales of Illegal and Counterfeit Drugs in the United States

Two individuals have admitted to engaging in a fraud involving an illegal Internet pharmacy and the dispensing of unapproved and mislabeled drugs of Indian origin to U.S. consumers who thought they were buying genuine brand-name goods. The prosecution – an unusual one spearheaded by FDA’s Office of Criminal Investigation (“OCI”) – underscores the continuing problem of the exploitation of U.S. consumers by the operators of illegal pharmacies, and the threat to public health posed by counterfeit and illegal medicines, including generics. The prosecution raises the question of what more can be done by the Government and by drug manufacturers to address this problem.

Notwithstanding points of vulnerability, notably in connection with secondary wholesalers and “gray market” goods, the legal U.S. drug supply chain is reasonably secure: Consumers who visit their local pharmacies or order branded medicines through mail pharmacies, typically offered under drug benefit plans, are overwhelmingly likely to receive genuine goods. Rather, the greatest challenges to the integrity of the system and to public health exist outside lawful drug distribution system, through purchases of drugs from Internet pharmacies that are not regulated by U.S. or in many cases any governmental agency. Criminal prosecutions in this area, as well as civil actions by manufacturers whose reputational and commercial interests may have been injured, are unusual. The unfortunate result has been the creation of a criminal class that believes it can engage in unlawful conduct, and jeopardize public health, with impunity. It is against this background that the March 16, 2009 guilty pleas by Randy T. and Sheila French, who operated a company called Prescription Buyers Group, Inc. (“PBG”), are a welcome development. So too it is a reminder of the role that brand name drug manufacturers can play in encouraging enforcement of the nation’s criminal laws and pursuing civil remedies that serve to protect not only public health but also the commercial interests of the manufacturers of the products in question.

The *French* case involved a U.S.-based fraud involving the sale of misbranded and unapproved drugs to consumers who believed that they had ordered genuine branded drugs, at highly discounted prices, over PBG’s website and through follow-up “800-number” conversations. PBG neither asked for nor received a prescription from the customer. It promised to dispense brand name drugs but filled orders with unapproved illegal drugs made in India – possibly unapproved generic versions of the brand name drugs, but the indictment says nothing about what the pills contained. In an apparent effort to create a favorable “name association” while steering clear of an explicit trademark violation, the illegal drugs sent to consumers bore names that were in many cases confusingly similar to the brand names or their active ingredients – “Sialis” for “Cialis®,” “Pfiagra” for “Viagra®,” and “Finpecia” for “Propecia®” – among others. None of the drugs sent to consumers was accompanied by package inserts or instructions for use. The Indictment alleges sales by PBG of approximately \$2.5 million over an 18-month period, and transactions involving fourteen drugs – both “lifestyle” and life-saving – made by seven major international drug manufacturers.

The prosecution was made possible with encouragement and substantial technical support from the companies involved, as well as from our client, the Pharmaceutical Security Institute, the drug industry’s anti-counterfeiting trade group.<sup>1</sup>

The Indictment alleged substantive violations of the Federal Food, Drug, and Cosmetic Act in connection with introducing or delivering for introduction into interstate commerce a misbranded drug<sup>2</sup> (21 U.S.C. § 331(a)), causing drugs held for sale after shipment in interstate commerce to be misbranded (21 U.S.C. § 331(k)), and introducing into interstate commerce an unapproved drug (21

U.S.C. § 331(d)). The defendants were similarly indicted for conspiracy to engage in the foregoing violations of law as well as violations of a number of other statutes, including smuggling (18 U.S.C. § 545), mail fraud (18 U.S.C. § 1341), and wire fraud (18 U.S.C. § 1343). The Frenches pled guilty to conspiracy and introducing misbranded drugs into interstate commerce, and agreed to forfeit to the United States all of their ill-gotten gains from PBG's operations. They also face jail terms of up to eight years in prison, as well as fines.



Evaluating instances of illegal Internet sales of drugs to U.S. consumers tends to be a very fact-specific exercise, in that governmental prosecution and the rights and remedies available to individual manufacturers will vary substantially from case-to-case.

The *French* case had a number of features that made it attractive to FDA's OCI. First, and probably most important, it was a relatively unusual example of a U.S.-based fraud. Typically illicit Internet pharmacies operate offshore, and OCI has been extremely reluctant to pursue them in U.S. courts despite substantial legal precedent that would allow U.S. courts to assert jurisdiction over foreign entities that had targeted U.S. citizens for criminal activity. In addition, the element of fraud and deception facilitated prosecution, and introduced an element of counterfeiting that took the case into the realm of ones that pose the greatest risk to U.S. consumers.

Many illegal Internet operations are like the one described in the *French* case, in which customers are led to believe that they will receive genuine goods, but the facts can take many shapes. As here, some illegal Internet pharmacies dispense drugs bearing names that are confusingly similar to those of branded drugs. Consumers may also receive counterfeit drugs bearing fake brand-name markings, or genuine drugs that have been illegally diverted from foreign markets and whose sale in the U.S. is both unregulated and illegal, or genuine goods diverted from U.S. customers by theft and whose handling has been unregulated, or genuine drugs bearing counterfeit labeling suggesting, for example, an incorrect potency. Sales of purportedly genuine drugs may also be filled with unmarked drugs that are unapproved generics, and whose safety and effectiveness have never been tested. Still other cases are ones in which no claim is made that genuine branded goods are available, but instead consumers are directly offered illegal and unapproved generics, sometimes upon the false representation that the drugs are legal.

From the manufacturer's standpoint, PBG's and related deceptions create concerns on a number of fronts. Commercially, manufacturers face lost sales and a risk to their reputations and the reputations of medicines copied by products whose quality is unknown. Potential product liability concerns also exist.<sup>3</sup> Beyond this, consumers are routinely duped into thinking that their efforts to save money on prescription drugs do not come with a risk that they are taking their lives into their own hands. In many cases, though, this is precisely the case. The fact that it is often difficult after the fact to pinpoint injuries attributable to drugs that are subpotent, or superpotent, or contain unintended active ingredients or dangerous chemicals, or have been handled improperly, only underscores the need for diligent enforcement of law by both the Government and drug manufacturers.

Given the ubiquity of Internet pharmacies, the *French* case reflects the inadequacy of law enforcement efforts to protect U.S. consumers from illegal drugs – be they counterfeit, unapproved generics, mislabeled, or even genuine drugs illegally diverted from their intended recipients. Manufacturers have had some success in bringing evidence of illegal conduct to the attention of FDA, DOJ entities targeting IP crimes, and local police. Some – an increasing number – have also recognized that civil actions can be used to deter illegal sales and provide information necessary to support prosecutions, perhaps on an international basis. The legal theories available to manufacturers include the following, whose applicability will turn on the facts:

- Patent infringement (35 U.S.C. § 271(a));
- Trademark infringement (15 U.S.C. § 1114(1));
- Trademark Counterfeiting (15 U.S.C. § 1116(d));
- Importation in violation of IP rights (19 U.S.C. § 1337);
- False advertising 15 U.S.C. § 1125(a);

- Trademark infringement (15 U.S.C. § 1124)
- Violations of the Tariff Act (19 U.S.C. § 1526(a))
- Trademark dilution (15 U.S.C. § 1125(c));
- RICO (18 U.S.C. § 1964); and
- State-law theories of unfair competition, tortious interference with contract, deceptive trade practices, consumer protection, among others.

Additional remedies, based on violations of the Food, Drug, and Cosmetic Act, wire fraud, mail fraud, and counterfeiting, would be available to governmental law enforcement officials.



Private and public enforcement actions against illegal medicines have not been as vigorous as the law would permit, and one consequence has been the emergence of large and profitable criminal enterprises whose members' indifference to public health is patent. Significant health risks do exist, however, and all responsible members of the lawful pharmaceutical industry should be committed to reducing them.

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1. Information about PSI, and about the worldwide problem of counterfeit drugs, may be found at [www.psi-inc.org](http://www.psi-inc.org).
  2. The drugs were alleged to be misbranded by:
    - Having labeling that failed to bear adequate directions for use (21 U.S.C. § 352(f)(1));
    - Being offered for sale under the name of another drug (21 U.S.C. § 352(i)(3)); and
    - Having been dispensed without a valid prescription (21 U.S.C. § 353(b)(1)).
  3. *See, e.g. Fagan v. AmerisourceBergen Corp.*, 356 F. Supp. 2d 198 (E.D.N.Y. 2004), *remanded*, 163 Fed.Appx. 37, 2006 WL 151807 (2d Cir. January 19, 2006).

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