

FDA's Evolving Civil Money Penalty Authority: Simple Violations Can Lead to Major Costs



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The U.S. Food and Drug Administration (FDA) has several enforcement tools at its disposal, including warning letters, injunctions, seizures and criminal prosecutions. While most industry professionals are familiar with these enforcement tools, FDA's civil money penalty (CMP) provisions may be less familiar to some. In the past five years, CMPs have emerged as an important enforcement tool as Congress has increasingly expanded FDA's authority to impose such penalties. With the expansion of FDA's CMP authority under the Food and Drug Administration Amendments Act of 2007 ("FDAAA"), the number of CMP cases will likely increase in the coming months and years.

Overview of FDA's CMP Authority

The FDA is authorized to impose CMPs for some, but not all, violations of the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Public Health Service Act (PHSA). Various statutory provisions grant FDA the authority to impose CMPs for specific violations. These include certain prohibited acts involving medical devices, prescription drug samples, generic drug approvals, pesticide residues in food, biological product recalls, mammography, electronic product standards and vaccines.

Historically, FDA has sought CMPs for continuous or repeated violations of the same or similar statutory requirements when other remedies such as seizure or injunction are not appropriate. Most CMPs are assessed through an administrative process. However, some CMP statutes authorize the U.S. Department of Justice to seek CMPs on FDA's behalf by filing a civil lawsuit in federal court.

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FDA's regulation, 21 CFR Part 17, sets forth the procedures for administrative CMP actions. These procedures are similar to federal court rules in many respects. FDA initiates CMP actions by filing a complaint with FDA's Division of Dockets Management. The plaintiff (known as a "complainant") is the FDA Center with principal jurisdiction over the product at issue - for example, a device CMP proceeding would generally be brought on behalf of FDA's Center for Devices and Radiological Health (CDRH). Once the complaint is filed, the defendant (known as a "respondent") has 30 days to file an answer. The parties also are permitted to seek limited discovery, file procedural and dispositive motions, participate in a hearing before an Administrative Law Judge (ALJ), and appeal ALJ decisions.

There are, however, notable differences in the CMP procedures as compared to federal court rules. For example, while either FDA or a respondent may appeal an ALJ decision to the U.S. Department of Health and Human Services Departmental Appeals Board (DAB), which has been designated to hear such appeals, only respondents may appeal a DAB decision to a federal appellate court. Additionally, ALJ's do not have the authority to find any federal statute or regulation invalid in the context of an administrative CMP proceeding.

While individual CMP statutes set forth the allowable range and specific violations for which CMPs are authorized, FDA retains considerable discretion in deciding when and against whom to seek CMPs. Both corporations and individuals can be respondents, and FDA has, consistent with the principles underlying the

Park Doctrine, sought CMPs against individual company executives who bear a responsible relationship to the alleged violations. In the case of CMP assessments against “small entities” (generally, independently owned and operated companies that are not dominant in their field), penalties may be reduced under the terms of the Small Business Regulatory Enforcement Fairness Act of 1996. CMPs are paid to the U.S. Treasury and not to the FDA.

FDA's New CMP Authority

The broad expansion of FDA's authority under the “drug safety” provisions of the FDAAA has spurred renewed interest in CMPs. In response to public concerns about product safety, Congress authorized FDA to impose significant drug safety obligations on industry. The FDAAA authorizes FDA to require Risk Evaluation and Mitigation Strategies (REMS) for drugs, both prior to and after approval. FDA may require a REMS if the Agency determines that a risk evaluation and mitigation strategy is necessary to ensure that the benefits of a drug outweigh its risks. Independent of the REMS framework, the FDAAA also authorizes FDA to require post-approval studies in light of “new information” about the product which could signal a serious risk. The FDAAA authorizes penalties for violations of REMS and study requirements and for violations of certain other requirements, such as the failure to comply with clinical trial registration requirements and violations involving direct-to-consumer (DTC) advertising, including false and misleading DTC advertisements. Violations of REMS and study requirements can result in CMPs of up to \$250,000 per violation in certain circumstances. Violations involving clinical trial registration requirements can result in CMPs of up to \$10,000 per violation. DTC violations may result in CMPs of up to \$250,000 for the first violation in a three-year period and up to \$500,000 for subsequent violations in a three-year period.

Recent CMP Cases

Prior to passage of the FDAAA, FDA filed a number of CMP actions involving device-related violations. Two recent CMP cases - in re TMJ Implants, Inc. and in re Advanced Bionics, Inc. - illustrate the types of factual situations in which FDA may pursue CMPs.

In Re TMJ Implants, Inc.

In July 2005, FDA filed a complaint seeking CMPs against TMJ Implants, Inc. (TMJI), its President, and its Regulatory Affairs Manager for repeated failures to file medical device reports (MDRs). The complaint alleged that, between 2002 and 2003, the company failed to file twenty-one MDRs relating to “serious injuries” associated with its temporomandibular joint implant devices (TMJ devices). FDA initially sought \$210,000 in CMPs (\$10,000 for each violation) against the corporation and each individual, but subsequently reduced the number of violations from twenty-one to seventeen, with a corresponding penalty reduction of \$170,000 for each respondent. In 2007, after extensive pre-hearing proceedings and a hearing on disputed factual issues, the ALJ assessed civil money penalties against each respondent in the amount of \$170,000. The company subsequently appealed the ALJ's decision to the DAB. The DAB affirmed the penalty assessment for the company and its President, but dismissed the CMP assessment for the regulatory manager on the grounds that she lacked sufficient decision-making authority with respect to the MDRs at issue in the case. TMJI appealed the decision to the U.S. Court of Appeals for the Tenth Circuit. A final decision was not reached at the writing of this article.

In Re Advanced Bionics, Inc.

In November 2007, FDA filed a complaint against Advanced Bionics, Inc. and two individual officers (the Chairman/Co-CEO and the President/Co-CEO). The complaint, which was amended in March 2008, alleged that the company shipped cochlear implants to U.S. customers without first filing a supplement to its Premarket Approval Application (PMA) to notify FDA of a change in a component supplier. FDA alleged that the company's failure to submit the information prevented the Agency from being able to evaluate the potential impact of the changes on the safety and effectiveness of the device. As a result, FDA considered the devices

adulterated. In July 2008, Advanced Bionics and its President/Co-CEO reached a settlement with FDA. Under the terms of the settlement, the company agreed to pay \$1.1 million in civil money penalties and its president/CEO agreed to pay \$75,000, without admitting liability for the violations described in the amended complaint.

The Future of CMPs

The safety and efficacy of regulated products features prominently in the agendas of both Congress and the Obama administration. For industry, FDA's ever-expanding authority to assess CMPs and the recent CMP actions involving individual corporate officers are yet another reminder of the need for careful management review and oversight of critical compliance and product safety requirements.

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