

A Guide for FDA Whistleblowers

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The [U.S. Food and Drug Administration \(FDA\)](#) is the federal agency that regulates food and pharmaceutical safety, as well as products and services that are adjacent to these areas, such as medical devices and cosmetics. While the FDA is a massive federal agency, the industries it regulates are even bigger. Hence, it needs whistleblowers to report signs of misconduct, fraud (including those leading to a substantial and specific danger to public health or safety related to the implementation or use of covered funds), waste, or abuse of authority relating to a federal contract as often as possible.

Becoming an FDA whistleblower, though, is a difficult decision to make. Here are four things to know before committing to it.

1. You are Insulated from Retaliation

The biggest concern that most whistleblowers have is whether they can face retaliation the workplace for reporting their misconduct to the FDA. This is particularly true when you find that it is your employer, who is the federal employee responsible for the misconduct. You may be blowing the whistle on a scheme that is making your company a lot of money.

Legally, whistleblower statutes include anti-retaliation provisions that make it unlawful for your employer to retaliate against you for lawful whistleblowing activities. The nature, extent, and scope of those protections vary by statute. The two most commonly used whistleblower laws for FDA fraud, waste, or abuse are the following:

1. [Whistleblower Protection Act of 1989 \(WPA\)](#)
2. Section 1013 of the Food, Drug, and Cosmetic Act (FD&C) ([21 U.S.C. § 399d](#))

For example, while the Whistleblower Protection Act protects you from retaliation that is related to your lawful whistleblowing activities (members of the U.S. Public Health Service Commissioned Corps are protected under the Military Whistleblower Protection Act), the FD&C Act also protects you when you:

- Testify to the Department of Justice, other law enforcement agency, or the Government Accountability Office, a federal employee responsible for grant oversight at the relevant

agency, or assist in a legal proceeding concerning an alleged violation of food or drug safety laws or FDA regulations

- Objected to or refused to participate in an activity that you reasonably believed to violate one of those laws or regulations

Practically, though, just because it is unlawful for your employer to retaliate or discriminate against federal contractors, subcontractors, and personal services contractors for blowing the whistle on FDA fraud, waste, or abuse does not mean that they will not do it, anyway. If they do, though, these federal whistleblower statutes provide them with legal redress.

For example, the FD&C Act lets you file a protected disclosure with the Department of Labor. Suppose the Department's investigation finds that you were unlawfully retaliated against for your whistleblowing activities. In that case, you can get reinstated and receive back pay and compensation for the other losses you suffered that were associated with the retaliation. On the other hand, the Whistleblower Protection Enhancement Act of 2012 prohibits agencies from issuing or enforcing non-disclosure agreements, policies, or forms against current or former employees. While the Intelligence Identities Protection Act governs protected disclosures that could expose confidential government agents.

2. You Can Receive a Portion of the Case's Proceeds

In addition to benefiting from the legal protections against retaliation, whistleblowers can also recover an award that is comprised of a share of the case's proceeds.

Generally, the award is between 10 and 30 percent of what gets recovered. Where you would fall in that range of percentages depends on whether:

- The FDA intervened in your case, or you prosecuted it all on your own
- There are multiple whistleblowers
- The evidence that you provided was a major or a minor contribution

However, the whistleblower statute you use to advance your case can also influence the amount of your reward. For example, whistleblower cases that use the [False Claims Act](#) recover the amount defrauded, plus a civil penalty for each fraudulent claim. That amount is multiplied by three, as the Act imposes treble damages.

This can lead to huge totals, which mean substantial whistleblower awards, even for whistleblowers who only get 10 percent of the case's proceeds. Unfortunately, the False Claims Act is a relatively rare vehicle for FDA cases because it only covers fraud against a government program. However, if you are blowing the whistle on, say, false statements made in the performance of a government contract, the False Claims Act may be available.

3. Having a Whistleblower Lawyer on Your Side is Critical

The variety of FDA whistleblower statutes that are available is just one of the reasons why [whistleblowers really need a lawyer](#) to guide them through the process. In many cases, the differences between the statutes are great enough that they can have a substantial impact on the outcome of your case.

That is just the beginning, though.

Chances are extremely high that this is your first time as a whistleblower. The investigation that you will conduct to unearth evidence of waste, fraud, or abuse in the system will be sensitive and could leave you exposed to serious professional consequences. Without the experienced guidance of a whistleblower lawyer who has done these investigations before, the odds are much higher that you make a misstep that proves to be costly.

4. Whistleblower Cases Follow a Unique Process

That investigation that you do is just one of the first steps in what can be a long process.

After they initially find signs of FDA waste of federal funds, fraud within the federal government, mismanagement of federal contract, or abuse, potential whistleblowers generally look closer to see if their suspicions are true or not.

If they are confirmed, the next best step is to get a whistleblower lawyer. Doing this before you investigate too much on your own can avoid the potential that you make a mistake. A lawyer can also point you in the direction of more and better evidence to gather or show you investigative techniques that you did not know.

When you have obtained as much evidence of misconduct as possible, the next step is to report it to the FDA and urge them to act on it. Even though it can decrease the whistleblower award that you are entitled to receive for disclosing the incriminating information, if the FDA intervenes in your case, then the investigation that they perform will be exceptionally thorough, and, more importantly, you and your legal team will not have to do it. Cases in which the FDA intervenes are substantially more likely to succeed than those that whistleblowers prosecute on the FDA's behalf.

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National Law Review, Volume XIV, Number 53

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