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HB | Legal Report Series

THE PHARMA WHISTLEBLOWER

8 STEPS *to* STOP PHARMACEUTICAL FRAUD *and* EARN *a* REWARD

About This Guide

If you have knowledge of a domestic or international pharmaceutical manufacturer, compounding pharmacy, drug company or distributor involved in FDA CGMP violations, mislabeled drugs, misrepresented product ingredients, adulterated products or defective medical devices, you may be eligible for a large cash award.

In order to help put a stop to this dangerous misconduct, it is important to (1) recognize which FDA violations constitute a "false claim," (2) understand your rights as a whistleblower, and (3) familiarize yourself with the FDA Pharma Whistleblower claims process.

A quick and easy reference for:

- FDA violations susceptible to FCA liability
- Legal rights of FDA Pharma Whistleblowers
- Steps to filing a FDA Pharma Whistleblower claim
- How to maximize your financial compensation

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U.S. Government Recruits Insiders to Fight Bad Pharma

Over the last 18 years, pharmacists filled some 112 million prescriptions with drugs that turned out to be contaminated, under-potent, over-potent or otherwise unsafe [International Journal of Health Services]. And those are just the medications that the U.S. Food and Drug Administration (FDA) knows about. Millions more unsafe drugs are circulating in and out of pharmacy shelves daily.

There are several reasons for the poor state of U.S. pharmaceuticals, all of which come down to time and profits. First, over 177 million Americans take at least four prescription medications regularly, not including over-the-counter drugs, vitamins, and supplements [Consumer Reports].

With this enormous demand, drug manufacturers are pressured to keep up the pace, often cutting corners in quality control and ignoring FDA current good manufacturing practice (CGMP) requirements.

Second, 80% to 85% of prescription drugs are now manufactured overseas, usually in China or India. This international pharmaceutical supply chain makes efficient pharmaceutical regulation tougher and tougher. Many Chinese and Indian factories aren't heavily regulated and have no reason to maintain a sterile environment or conduct regular quality control testing.

Some reports suggest that up to 40% of drugs manufactured in India are "sub-standard."

Many dishonest drug manufacturers will try to save money by diluting medications with a filler or skimping on testing batches for appropriate doses of primary ingredients. They will also hide bad test results to avoid embarrassing

recalls. The media attention one recall receives can persuade millions of consumers to switch to an alternate medication made by a different company.

In addition, the FDA is understaffed. Inspectors are barely able to inspect major manufacturing facilities every two years. And when they do, companies often know about the inspection months in advance, giving them time to clean up, falsify testing data and hide non-compliance.

When dishonest pharmaceutical companies receive FDA warning letters, they either ignore them or lie to the FDA and hide evidence of CGMP violations. There is simply no way the FDA can effectively monitor every pharmaceutical manufacturing facility.

Because of the significant threat to public health and taxpayer dollars, the FDA, Department of Justice (DOJ), and Department of Health and Human Services Office of the Inspector General are actively recruiting insiders – those who work within these companies – to detect and report drug manufacturing violations.

By utilizing federal and state False Claims Acts, the government is able to offer large financial incentives to insiders who chose to come forward.

A string of recent False Claims Act successes involving FDA CGMP violations has prompted increasing numbers of pharmaceutical industry workers to come forward with knowledge of FDA violations, adulterated pharmaceutical fraud, and other drug manufacturing fraud.

Common FDA Pharma Whistleblowers include former and current:

- Drug or medical device quality assurance (QA) professionals
- Drug calibration specialists

- Pharmaceutical sales representatives
- Public health administrators
- Drug manufacturing and medical device company executives
- Other drug safety or quality control specialists

Both domestic and international whistleblowers who report FDA CGMP violations, fraudulent neglect of safety standards, ingredient misrepresentations, defective medical devices, and policies that promote deceitful FDA reporting may qualify for a large cash whistleblower award.

More importantly, these courageous heroes help stop the dangerous practices of careless pharmaceutical manufacturing, potentially saving lives.

But blowing the whistle on Big Pharma can be a complex, daunting process. Whistleblowers must take careful precautions to safeguard their personal lives and careers while working to maximize their cash award. If you are considering becoming a Pharmaceutical Whistleblower, this 8-Step Guide to FDA Pharma Whistleblower Lawsuits can help get you started on the right track.

Questions About Your FDA Pharma Whistleblower Claim?
Contact Halperin Bikel at 929.290.1266 or Visit
www.uswhistleblowerlawyer.com

How Does the FDA Regulate Drug Manufacturing?

Under the Federal Food, Drug and Cosmetic Act, the FDA regulates not only the manufacturing of prescription medications but also many of the component ingredients.

The Act requires that pharmaceutical suppliers of active pharmaceutical ingredients (APIs), intermediates and excipients follow current good manufacturing practices (CGMP) in the manufacturing, processing, packing, and storage of these raw materials [21 C.F.R. §210].

In addition, the FDA requires that pharmaceutical laboratories establish scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity [21 C.F.R. §211].

Through its CGMP regulations, the FDA also regulates raw material acquisition, facility equipment maintenance, staff qualifications, quality management systems, standard operating procedures (SOPs), testing lab operation, sterile environments, and data and quality control records protocols (you can find FDA pharmaceutical manufacturing guidelines in C.F.R. Title 21, §§ 1-99, 200-499, and 600-1299).

Though international facilities manufacture a majority of the APIs and excipients that are sold to U.S. formulators today, they are still subject to FDA regulations and must produce the same standard of quality as any domestic manufacturer.

Typically, when an FDA inspection or complaint suggests that a pharmaceutical supplier is manufacturing FDA-regulated products without meeting CGMP requirements, the FDA will take several actions.

In cases that don't pose an immediate threat to public safety, the FDA will issue a Form 483 to notify the company of the findings. If the company doesn't respond, the FDA will issue a warning letter and give the facility a

chance to correct the violations. If the misconduct continues, the FDA can ban products from U.S. importation or order the facility to stop producing until they can prove CGMP compliance.

Under the Federal Food, Drug and Cosmetic Act, a drug or device produced in non-compliance with FDA CGMP regulations is considered "adulterated." Once the FDA issues a warning letter regarding CGMP non-compliance, the drug in question can be considered adulterated.

The Food, Drug and Cosmetic Act prohibits any adulterated drug from being introduced (or delivered for introduction) into interstate commerce. Pharmaceutical companies that don't comply with FDA CGMP regulations are in violation of the Federal Food, Drug and Cosmetic Act and can face both civil and criminal penalties.

All the government has to prove to prevail on an adulteration charge is that the manufacturer failed to comply with CGMP regulations. The drug doesn't actually have to be faulty or substandard in quality or purity.

Examples of FDA CGMP Violations

If you work in pharmaceutical manufacturing, you have likely had FDA CGMP regulations drilled into your brain. Most U.S. facilities hold regular compliance meetings to ensure everyone understands what is expected. They may also conduct regular, relaxed internal inspections to determine how compliant they are with FDA regulations.

You will likely have an employment manual stating FDA CGMP regulations. You can also find FDA pharmaceutical guidelines in C.F.R. Title 21, §§ 1-99, 200-499, and 600-1299.

Briefly, here is a list of examples that constitute FDA CGMP violations (taken from several FDA warning letters):

- Analytical anomalies (like relying on assay results obtained from the average of two independent sample results when one of the sample results was out of spec (OOS)
- Destruction of batch record documents prior to one year following expiration
- Failure to establish and follow procedures to prevent contamination of sterile products
- Failure to establish written control protocols that ensure product strength, purity, and quality
- Failure to investigate OOS batches, and then examine other batches and products associated with the spec failure
- Failure to investigate repeated contamination
- Failure to maintain validated computer systems
- Failure to propose corrective action and review other production records to ensure no additional incidents
- Failure to reject test batches OOS for identity, strength, quality and purity
- Failure to review and approve all drug production records for compliance before release
- Failure to routinely and appropriately maintain manufacturing equipment
- Failure to write validation protocols, isolate process parameters, and demonstrate that product performance is consistent and reproducible from batch to batch
- Omission, addition or alteration of raw data from lab control records
- Poor cleaning and sanitization practices
- Poor electronic data management

- Preparing, packing and holding products in unsanitary conditions
- Significant deviations in bulk drug substance and drug component manufacture
- SOPs are outdated, aren't CGMP compliant or aren't readily accessible
- Unqualified, untrained or inexperienced employees engaged in the manufacture, processing, packing or holding of a drug
- Using lots prior to testing and quality control approval

Unfortunately, many pharmaceutical companies are in dangerous violation of FDA CGMP regulations.

Several years ago, many Americans were killed after Baxter Pharmaceuticals relied on a Chinese producer to make its heparin API. The FDA alleged the supplier used a chemically similar, but medically worthless, ingredient to pass quality control testing. Again, it likely came down to money. There was a huge difference in cost between the real heparin API ($900 per pound) versus the fake ($9 per pound).

In a 2016 inspection of a Vista Pharmaceuticals plant in India, FDA investigators found corroded manufacturing equipment. Prior to the inspection, the FDA received a complaint about Isoxsuprine hydrochloride (Vasodilan) pills that were shipped to the U.S.

The pills contained metal fragments.

It turns out that Vista never bothered getting the Isoxsuprine approved, nor did it submit a validation process for the drug manufacturing process to the FDA.

If you have knowledge of FDA CGMP violations, mislabeled drugs, misrepresented product ingredients, adulterated products or defective

medical devices, our Halperin Bikel FDA Pharma Whistleblower lawyers can help protect your rights and maximize your cash award.

Contact Halperin Bikel at 929.290.1266 or Visit
www.uswhistleblowerlawyer.com

How Does the FCA Apply to FDA Violations?

Companies that fail to comply with FDA regulations not only violate the Federal Food, Drug and Cosmetic Act. They may also be in violation of federal and state False Claims Acts (FCAs). When this is the case, you may be eligible for a cash whistleblower award.

The government doesn't like the fraud, waste, or abuse of taxpayer dollars. And manufacturing substandard products that are paid for by taxpayer-funded programs like Medicare, Medicaid, or TRICARE is exactly that.

When these programs are billed for adulterated drugs, each bill is considered a "false claim." Medicare, Medicaid, and TRICARE guarantee a certain standard of service and performance. Anything that falls below that standard doesn't qualify for payment – including adulterated drugs.

Pharmaceutical companies may violate the FCA by selling adulterated drugs, or by receiving funding from Medicare or other government-funded programs to produce products. Medical device manufacturers are equally susceptible to FCA liability.

Under the federal False Claims Act, companies who provide substandard products (that violate FDA CGMP regulations) must pay a fine of $11,000 to

$21,000 per false claim in civil penalties, plus three times the government's damages [31 U.S.C. §3729].

Considering the number of prescription medications billed to these programs, this amount can easily fall in the ten-million to hundred-million-dollar range.

For example, if a drug manufacturer makes an adulterated drug, causing the submission of $20 million in false claims to Medicare, that drug manufacturer could be liable for damages of up to $60 million – plus a civil penalty of up to $21,000 for each and every prescription of adulterated drugs Medicare paid for.

If 10,000 bottles of the adulterated drug were paid for by Medicare, the drug manufacturer could be fined a civil penalty of up to $210 million dollars – plus the $60 million in damages.

This is where the financial incentive for blowing the whistle comes in. Under the FCA, when a whistleblower's original source information leads to a successful government settlement or verdict, the whistleblower is entitled to collect between 15% and 30% of the total government recovery.

In the example above, if a QA officer was the one to discover the CGMP violations and report the fraud, that QA officer could collect between $40.5 million and $81 million in a cash whistleblower award.

In 2017 alone, the federal government paid out $635 million to whistleblowers. This is how seriously the government takes whistleblowers and the life-saving information they can provide. Without the specialized knowledge of persons working from the inside of these facilities, the government would be significantly less likely to learn of fraud, waste or abuse of taxpayer dollars.

Without the aid of pharmaceutical whistleblowers, the risk to public safety would be exponentially higher.

Whistleblower complaints are filed under seal, meaning they are secret while the case is being investigated by the government. And you don't have to pay any legal fees unless you receive an award. If you have knowledge of fake or adulterated pharmaceutical drugs being marketed in the United States, call Halperin Bikel immediately for a free, fully confidential consultation.

Contact Halperin Bikel at 929.290.1266 or Visit
www.uswhistleblowerlawyer.com

What Whistleblower Protections Are Available?

With the massive cash awards and the potential to stop harmful fraud, why don't more people blow the whistle? For many, the answer is fear - fear of company retaliation, fear of career destruction.

Retaliation is an unfortunate reality for the pharmaceutical whistleblower. Colleagues may ostracize you. You may be harassed or even fired. You may be transferred, demoted, denied a promotion, or discriminated against in some other way.

The government knows how hard blowing the whistle can be. So they have included several provisions in the False Claims Act to protect whistleblowers and correct any adverse action taken against an employee who raises concerns.

First, despite what your employment agreement may say regarding HIPPA violations and releasing internal information, the HIPPA Privacy Rule

has a strong exemption for those who chose to report misconduct. Many pharmaceutical companies use the threat of prosecution for HIPPA violations to keep their employees quiet.

But know that any protected information that suggests misconduct can legally be shared with an FDA Pharma Whistleblower lawyer or public health agency.

Second, the FCA protects whistleblowers by requiring that claims be initially filed under seal. This means the defendant will not be made aware of any whistleblower claim for at least 60 days. During this time, the government will conduct its investigation into your claim. If the government needs more time, they can obtain an extension. In some cases, a whistleblower claim may remain under seal for years. (Expect the case will be under seal at least six months or more.)

Once the investigation concludes, the case will be unsealed, at which point you may become identified as the whistleblower. But this window of anonymity is very helpful for individuals who want time to prepare for any repercussions or seek other employment.

In addition, both federal and state whistleblower laws have powerful anti-retaliation provisions. Under the federal FCA 31 U.S.C. §3730(h), it is illegal for any company to discharge, demote, suspend, threaten, harass, or in any other manner discriminate against an employee in the terms and conditions of employment because the employee has sought to stop an employer from engaging in misconduct.

Any individual who experiences retaliation from their employer for attempting to report misconduct, whether internally or to an outside source,

can file a claim for damages. These damages may include job reinstatement at the same level of seniority, twice any amount of lost wages or backpay, and compensation for any "special damages" incurred as a result of the retaliatory treatment.

Whether you report to save a life or collect a reward, stopping counterfeit drugs from entering our stream of commerce makes you a hero. To date, we have helped our hero clients collect over $100 million in awards. You could be next.

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8 Steps to a Successful FDA Pharmaceutical Whistleblower Claim

FDA whistleblower claims are a complex process, with many potential snares. You must know how to protect your original source information, how to gather evidence legally, and how to navigate some challenging procedural processes.

But a successful FDA Pharma Whistleblower claim also comes with numerous rewards - a large financial award, the ability to replenish misspent taxpayer dollars, and the power to stop potentially deadly medications from entering the market. It also means knowing that you made a difference.

By following these 8 Steps to Stop Pharmaceutical Fraud and Earn a Reward, you will be off to a solid start.

Step #1: Contact an Established Whistleblower Lawyer Immediately

From the moment you suspect a pharmaceutical company of committing an FDA CGMP violation, before you do anything else, find an experienced whistleblower lawyer that understands False Claims Act cases and has a solid track record. Don't be shy about asking your lawyer to discuss his or her track record, experience, and willingness to try the case if the government declines to prosecute.

Don't worry about lawyer fees. Whistleblower cases are typically handled on a contingency or "success" fee basis, meaning the lawyer earns nothing if you do not get an award.

A reputable whistleblower attorney won't ask for any fees upfront. Your lawyer will provide all expenses and only collect their fee when you collect your cash whistleblower award.

Make sure you contact a lawyer before you report your suspicions to your co-workers, supervisors, other internal sources and before you begin collecting documents or other evidence. Do not call government agencies or hotlines until you speak with a lawyer.

Reporting fraud to an agency or hotline won't get you an award and may even diminish your chances for recovery.

An established attorney will be able to help you:

- Decide whether you have a potential FCA case
- Estimate how much reward money you may be eligible for

- Protect your identity and career
- Protect your original source information
- Handle special challenges regarding highly confidential documents
- Decide what documents or evidence are helpful for your case
- Determine whether you can legally obtain evidence
- Organize and file a persuasive claim
- Coordinate a government review
- Adhere to procedural requirements
- Maximize your cash award amount
- Pursue an anti-retaliation claim if necessary

If you have knowledge of a domestic or international pharmaceutical manufacturer, compounding pharmacy, drug company or distributor that is involved in FDA CGMP violations, mislabeled drugs, misrepresented product ingredients, adulterated products or defective medical devices, you will need to act quickly. Reporting is competitive, and the FCA strongly favors the first whistleblower to report a fraud.

First-to file requirements apply. Statutes of limitations in FDA Pharma Whistleblower lawsuits are complex and highly dependent on each specific case. Your lawyer will be able to make certain you meet all deadlines to solidify your role as whistleblower.

Step #2: Determine Whether A False Claim Exists

In order to qualify for a whistleblower award under the federal False Claims Act, you must show that a false claim has been made against the government. Your lawyer will be able to determine whether that potential exists by considering the extent of the FDA CGMP violation(s) and the involvement

of your company in government programs like Medicare, Medicaid, or TRICARE.

Note that not all FDA CGMP violations will qualify for FCA liability. Innocent mistakes aren't usually FCA liable since FCA liability requires that the defendant act with deliberate ignorance or reckless disregard. Of course, gross negligence would be of concern to the court.

While CGMP violations that result in a foreseeably hazardous or less effective product entering the market would certainly have the potential for FCA liability, a bad product is in no way required to result in false claims.

Merely lying to cover up non-compliance is enough to establish a false claim. For example, many false claims lawsuits arise for drug manufacturers who violate FDA regulations on written and electronic records and reports. These violations could include:

- Discarding production, control, and distribution records prior to 1 year after batch expiration date.
- Failing to maintain and respond to corrective and protective action (CAPA) data
- Failing to notify company officials (who may not be directly involved) of any recalls, FDA reports, or regulatory actions regarding FDA CGMP regulations
- Hiding certain records from FDA inspectors
- Making false statements regarding batch quality standards or equipment maintenance
- Omitting data from records that would be used to evaluate quality standards (batch approvals and rejections, complaints, recalls, returned or salvaged drug products)

An experienced FDA Pharma Whistleblower lawyer will be able to help you determine whether a CGMP violation could be FCA liable.

Step #3: Don't Talk to Anyone Except Your Lawyer

This includes strangers, friends, coworkers, government agencies, company ethics hotlines, and the media. Because most whistleblower awards must follow first-to-file guidelines, you could lose your whistleblower eligibility if someone else decides to report your suspicions about non-compliance.

Some whistleblower laws have a "public disclosure" prohibition. That means telling anyone could jeopardize your claim. Many courts have a sealing order issued by a judge, meaning that you could be sanctioned (fined, jailed, or other punitive action), and your claim dismissed for breaking confidentiality.

Remember, there is no such thing as "off the record."

In addition, putting information on the internet or speaking on the phone can be dangerous. Never call your attorney from a company phone or email documents from a work computer or using a work email account. There is little expectation of privacy and little legal protection of that privacy when you use a work computer, company telephone, or your employee email address.

If you have any uncertainty about whether to speak with someone, ask your lawyer first.

Step #4: Gather Evidence Legally and Confidentially

Solid evidence that suggests a successful recovery is vital to persuading the government to dedicate their time and resources to your case. But gathering evidence is a delicate process. You have to make sure you obtain documents legally, quickly, confidentially, and thoroughly.

Any evidence taken in violation of the law may not be admissible and may get you into trouble. At the same time, you will need to gather what you can quickly. It's not hard for coworkers or officials to pinpoint a potential whistleblower. You could be fired without warning and immediately (and permanently) lose access to your office and files.

Several types of evidence showing CGMP violations (and/or the attempt to hide those violations) can be helpful to your case.

- Batch test results
- Billing records
- Email communications
- Internal inspection records
- Raw study data
- Video / audio files

In general, evidence obtained from public sources (media, internet, published studies, published court documents) is not going to contribute to your case (unless your analysis of that information is original).

Create a safe place to log information, including specific dates, times, incidents, phone numbers, computer IDs, places, and names of relevant individuals that have any relationship to your original information regarding a potential

violation. Remember to keep information that may relate to a retaliation claim as well. (Don't keep your log at work or on a work computer – if you are suddenly terminated, you may not be able to access these records if kept at work.)

Never email yourself massive amounts of documents. Many companies have sophisticated IT programs that look for possible whistleblower activity by monitoring emails being sent to home email addresses. An experienced FDA Pharma Whistleblower lawyer can help you determine what documents or evidence are helpful for your case and whether you can legally take these documents from the workplace.

Step #5: Draft and File Your Whistleblower Claim

After you gather enough evidence to convince the government they could be dealing with false claims involving CGMP violations, your lawyer will help you organize this evidence to draft your claim, then help you to arrange a disclosure meeting with the government where you will convince them to get involved.

Next, you and your lawyer will file the claim in court and submit it to the government. Remember, the claim will be filed under seal so your company will not be notified that any action is taking place.

Step #6: Assist with the Investigation

Once the government decides to investigate your claims, they will begin collecting further evidence. Much of their initial evidence will come from you, and your whistleblower award amount increases with the level that you contribute to the government's investigation.

Keep a running log of any information you want to share with investigators during interviews and any potential names of witnesses you may want them to speak with.

Depending on the severity of your allegations, the government's investigation may involve the FBI and include full searches of the facility and associated facilities, numerous witness interviews and document searches. It is important that you cooperate to the best of your ability and remain available to investigators.

After the investigation, the government will decide whether or not to intervene in your whistleblower lawsuit. Should they choose to intervene, the whistleblower is eligible to collect between 15% and 25% of any government recovery.

Should they decline to intervene, the whistleblower is free to pursue the case on their own with the aid of their whistleblower lawyer (in some cases, the government may decide to intervene once the case gets rolling).

This is why hiring a lawyer who is willing to take your case all the way through trial is crucial. Switching lawyers mid-case can drastically harm your chances for success. Whistleblowers who achieve a successful settlement or verdict in cases where the government does not intervene are eligible to collect an increased award of between 25% and 30% of the total recovery.

Step #7: Prepare for Potential Retaliation

While every whistleblower's experience is different, there are a few things you can almost be certain of. Your identity will eventually become known,

you will experience some level of retaliation, and you will likely need (or want) a new job. Planning for these things in advance can help to lessen any stress associated with your whistleblower case.

Depending on the type of whistleblower case, your identity may never be released. However, we prepare our clients for the probability their identity and whistleblower status will eventually become known. When this happens, friends and coworkers may treat you differently. You may get calls from the media. Discuss these scenarios with your lawyer well in advance of the day it happens.

While employer retaliation in response to an employee reporting misconduct is illegal, many people who report misconduct either internally or externally will experience some form of discrimination in response to their actions. It's much easier to bear if you are prepared.

Both federal and state whistleblower laws have strong anti-retaliation provisions that compensate whistleblowers for retaliation - but they don't prevent it. They simply allow you to file a claim for job reinstatement, double backpay, and other special damages.

If your FDA Pharma Whistleblower attorney feels you have a strong case, it may be a good idea to start considering another job or career path. Anti-retaliation laws don't offer much immediate comfort if you suddenly find yourself without a job, and court battles can take years.

It's best to have a plan in place to support yourself and your family in case you are the target of retaliation. Unfortunately, your identity as a whistleblower can make it difficult to find a job within your same career path in the future.

These factors are always important to consider earlier rather than later. Often your whistleblower lawyer can help you keep your identity confidential, at least as to third parties and potential employers.

Step #8: Have Check in Hand before Spending the Money

Whistleblower cash awards can be significant. A majority fall into the hundreds of thousands to millions of dollars range. One of our recent FCA cases achieved a $154 million whistleblower cash award (a $1 billion settlement)!

This is exciting, and whistleblowers more than deserve these massive cash awards for their efforts. But remember, the case isn't over until the check is in your bank. FCA whistleblower cases require patience, and no matter how promising your case appears, it is important to remain financially smart.

Of course, it is fine - even advisable - to begin planning your estate and getting guidance from financial advisors on how best to handle your upcoming cash award, but don't make the mistake of spending more than you currently have.

While we can estimate your cash award amount, it is impossible to know the exact amount until you have it in your hands. The Court uses several factors to determine your exact award amount, including your ability to follow reporting requirements and required deadlines, the value of your information, the amount of damage resulting from the misconduct, whether or not the government intervened, the extent to which you aided the investigation, and the extent to which you participated in the misconduct (among other criteria).

Some folks are reluctant to step forward for fear that they may be prosecuted for participating in the wrongdoing.

That is rarely a problem if you were simply following orders or doing what you were told. Unless you were the mastermind of the scheme, there isn't much to worry about. But talk to your lawyer. A good whistleblower lawyer can help determine in advance if there might be a problem or if your conduct could impact the size of the award.

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The benefits of applying FCA actions to FDA CGMP violations are vast. FCA claims benefit the pharmaceutical industry itself, holding drug manufacturers accountable and leveling the playing field for those who comply with FDA regulations. Further, the FCA allows valuable government programs to put wasted and abused taxpayer funds back into the health care industry.

Most importantly, it helps to save lives.

Whistleblowers are central to the FCA system. Without them, pharmaceutical manufacturers continue to go unchecked, the cost of medical care continues to rise, and the lives of our loved ones and ourselves are put in danger. If you are considering blowing the whistle on FDA pharma fraud, we applaud you. Whistleblowers are a special, courageous breed of people and true American heroes.

Need more information? Give us a call. We have the experience and track record to pursue the most complex of False Claims Act cases. From small cases to billion-dollar recoveries, we are not afraid to tackle the world's biggest companies and seek the highest possible whistleblower awards.

Get Started on your FDA Pharma Whistleblower Claim Today
Contact Halperin Bikel at 929.290.1266 or Visit
www.uswhistleblowerlawyer.com

How to Select A Qualified Whistleblower Lawyer

Selecting your FDA Pharma Whistleblower lawyer could be the single most important decision you make.

The right lawyer can mean the difference between a successful whistleblower claim and the loss of your right to a cash award. Even more importantly, having the right lawyer to guide you through the process from the start can safeguard your job, career, reputation, and future.

Willingness to Proceed Without Government Intervention

Do not hire an employment or generalized lawyer, members of the so-called "file and forget" club. They file your case and simply hope the government pursues the case. A specialized FDA Pharma Whistleblower lawyer with years of experience is willing to take your claim all the way, whether the government opts to intervene or not.

Powerful Company Experience and Investigative Experts

Your FDA Pharma Whistleblower lawyer must be fully equipped to take on the most complex of FDA Pharma cases. This means being well-versed in whistleblower law, having experience with the nation's largest, high-power companies, and having access to the best investigative experts to help prepare your case.

Wide Jurisdictional Knowledge and Expertise

FDA Pharma Whistleblower cases, in particular, often span a number of jurisdictions. Twenty-nine states also offer awards. Our FDA Pharma Whistleblower lawyers work with clients worldwide and have filed cases in 37 states. This level of experience and scope of practice can be paramount in persuading the government to devote resources to your case.

Prepared to Pursue Your Claim Through Trial

Obtaining a False Claims Act whistleblower award requires filing a lawsuit in federal court. While that task sounds daunting to many lawyers, our team of experienced whistleblower lawyers has years of experience investigating claims, preparing complaints, and working with the Justice Department and investigative agencies.

Before filing, we often interview prosecutors to determine their level of enthusiasm, determine their resources, and find the jurisdiction with the best case law. If necessary, we even prosecute the case through trial.

Dedicated Employment Law Professionals for Retaliation Claims

Familiarity with the multitude of anti-retaliation laws is vital in handling FDA Pharma Whistleblower claims, especially when you are still employed by the company in question. Our whistleblower clients have first-hand access to our dedicated employment lawyer who helps to answer questions, mitigate risks, and guide our clients through every step of the process.

For any False Claims Act whistleblower claim, it is critical to prepare and plan your case in advance of reporting. The FDA, DOJ, and other agencies receive

thousands of complaints and only select a small percentage for prosecution.

At Halperin Bikel, our investigators and pharma experts work with our lawyers to prepare the strongest possible ready-to-go case before filing to maximize your chances and maximize your reward.

Contact Halperin Bikel at 929.290.1266 or Visit
www.uswhistleblowerlawyer.com

Frequently Asked Questions About FDA Pharma Whistleblowers

Who can be an FDA Pharma Whistleblower?

Anyone with information on FDA CGMP violations can file a whistleblower complaint, even third-party agents, outsiders, and international parties. You need not be a U.S. citizen or even a resident to receive an award. All you need is original source information of false claims against a government program.

Common FDA Pharma Whistleblowers include former and current drug or medical device QA professionals, drug calibration specialists, pharmaceutical sales representatives, public health administrators, drug manufacturing company executives, medical device company executives, and other pharmaceutical safety or quality control professionals.

Government employees are an exception. If you are a government employee and your duties primarily involve ferreting out fraud or misconduct, you may be ineligible for an award.

How do I know if I have "original source" information?

Original source information is information derived from the independent knowledge or analysis of the whistleblower. The information is not available to the regulatory agency through any other source and was not derived from allegations made in a judicial or administrative hearing, government report, audit, investigation, or news media.

How much evidence of non-compliance do I need to become an FDA Pharma Whistleblower?

Even the mere suspicion of FDA CGMP violations offers enough cause to contact a FDA Pharma Whistleblower lawyer, who can then confidentially evaluate your information and eligibility for a whistleblower award.

Most whistleblower programs do not require proof of intent to violate FDA Pharma regulations. Evidence suggesting the wrongdoer acted knowingly, with deliberate ignorance OR reckless disregard is often enough to file a whistleblower claim.

Can I report my information anonymously?

Initial consultations with an FDA Pharma Whistleblower lawyer are always kept confidential. A whistleblower's identity is normally kept confidential throughout the investigation.

If you choose to make a report directly to the FDA, anonymously or not, you are not eligible for an award. Only whistleblowers who comply with all requirements of the False Claims Act are eligible for awards.

Will my identity be kept confidential?

Under the False Claims Act, the whistleblower's identification is kept confidential for the first few months, then often revealed late in the investigation or when legal proceedings are initiated. Sometimes your identity can be shielded from third parties or the general public.

How do I apply for an FDA Pharma Whistleblower award?

Call an FDA Pharma Whistleblower lawyer immediately - before you report your suspicions to your co-workers, supervisor, or another internal source - before you contact the government or a hotline - before you begin collecting documents or other evidence. To be eligible for a whistleblower award, first and foremost, you must protect your information as an "original source." Do not share it with anyone but your lawyer.

Second, you must be the "first to file." If anyone reports your specific information, you lose your eligibility for the cash award. Your lawyer will lead you through the appropriate reporting procedures while safeguarding your information, protecting you from illegal retaliation, and helping to maximize your cash award amount.

How does the court determine my whistleblower award amount?

Because of the millions to billions of dollars in damage that FDA Pharma violations can cause, FDA Pharma Whistleblower awards often fall in the millions of dollars range. Determinations of the exact amount awarded to a whistleblower depend on the monetary range offered by each applicable statute.

Within that range, the court determines the exact whistleblower award amount based upon, (1) ability to follow reporting requirements and required deadlines, (2) value of information supplied by whistleblower, (3) amount of damage resulting from misconduct, (4) whether or not the government chooses to intervene, (5) extent to which whistleblower aids investigation, and (6) extent to which whistleblower participated in misconduct (among other criteria).

When will my employer learn that I have reported a violation?

In order to facilitate the gathering of evidence, companies under investigation are not often made aware of a whistleblower's identity until the investigation or legal proceedings require. Initial consultations with an FDA Pharma Whistleblower lawyer are always kept confidential.

What rights do I have if my employer retaliates against me for reporting a violation?

Numerous federal and state anti-retaliation protections are available for employees or other individuals who have reported misconduct (internally or externally) or assisted with an investigation regarding misconduct.

These protections allow employees or others who have been fired, demoted, harassed, threatened, denied a promotion, blacklisted, or otherwise discriminated against because they attempted to stop a violation to sue that employer for damages, often including back pay for lost wages and/or benefits, job reinstatement, and attorneys' fees and costs.

What does an FDA Pharma Whistleblower lawyer do?

The FDA Pharma Whistleblower lawyer is the single most important tool a whistleblower uses to obtain their cash whistleblower award. From the instance a whistleblower becomes suspicious of his or her employer's activities, to the point the whistleblower cashes the award check – and beyond - the FDA Pharma Whistleblower lawyer is helping direct their every move.

An established attorney will be able to help you:

- Decide whether you have a potential FCA case
- Estimate how much reward money you may be eligible for
- Protect your identity and career
- Protect your original source information
- Handle special challenges regarding highly confidential documents
- Decide what documents or evidence are helpful for your case
- Determine whether you can legally obtain evidence
- Organize and file a persuasive claim
- Coordinate a government review
- Prosecute the case in court if necessary
- Adhere to procedural requirements
- Maximize your cash award amount
- Pursue an anti-retaliation claim if necessary

What happens once I contact an FDA Pharma Whistleblower lawyer?

Your first consultation with a FDA Pharma Whistleblower lawyer often involves a confidential discussion around your suspicions or evidence of

misconduct, and whether or not your information makes you eligible for a cash whistleblower award.

Based on your specific information, your lawyer will discuss how best to proceed in a way that will protect your rights as a whistleblower – i.e., how to collect further evidence, how to keep notes on employer activities, how to craft language should you want to give your employer a chance to fix the problem before filing a claim.

Should you choose to file a claim, your lawyer will then assist you in preparing your case, meeting required deadlines, maximizing your award, and safeguarding your rights.

Are there time limits on filing a whistleblower lawsuit?

Yes! First-to file requirements apply in many cases. Statutes of limitations in FDA Pharma Whistleblower lawsuits are complex and highly dependent on each specific case. Your FDA Pharma Whistleblower lawyer will ensure that you meet all required deadlines.

If you have knowledge of a pharmaceutical manufacturer, compounding pharmacy, drug company, or distributor that is defrauding the FDA, Medicare, Medicaid, or Tricare, contact Halperin Bikel immediately. We are ready to help you stop the fraud or unsafe practices and to make sure you get the highest award possible.

I am not a US Citizen, can I still receive an FDA Whistleblower Award?

The answer is yes! With so many pharmaceutical companies located offshore, many whistleblowers from outside the United States are now

stepping forward to do their part to fight corruption and bad pharmaceutical practices.

I work at a compounding pharmacy regulated by the state. Am I eligible for an award?

Ever since the 25 tragic meningitis deaths that investigators believe were caused by unsterile conditions at the New England Compounding Center, both states and the FDA have been more actively monitoring conditions at compounding pharmacies. If a drug is produced at the pharmacy and eligible for Medicare / Medicaid / Tricare reimbursement, violations of CGMP and other regulations – state OR federal – are potentially eligible for awards.

What other awards are possible?

The federal False Claims Act described in great detail above is the primary whistleblower law in most pharmaceutical whistleblower cases. However, there are often other ways to collect an award.

Since most pharmaceutical companies are multinational corporations, they frequently do business in other countries. In fact, over three-quarters of the prescription drugs sold in the United States are manufactured offshore.

In many countries, bribery and government corruption are commonplace. The United States has very strong laws that prohibit bribery of foreign government officials. And unfortunately, several major drug companies have run afoul of these laws.

The law preventing foreign bribery is known as the Foreign Corrupt Practices Act (FCPA). Both the Securities and Exchange Commission (SEC) and the Justice Department enforce this law. Fortunately, the SEC has its own whistleblower program complete with robust anti-retaliation provisions.

Like the False Claims Act, SEC whistleblowers can earn up to 30% of what the government collects from wrongdoers. FCPA whistleblower awards are often millions of dollars.

Twenty-nine states also have their own state False Claims Act laws that cover Medicaid expenditures. Since most drugs covered by Medicare are also covered by Medicaid, it is often possible to collect multiple awards. A good FDA whistleblower lawyer knows these laws and knows how to make claims or file suits in the various states.

There is more! Two states have private insurance whistleblower laws that might include adulterated pharmaceuticals that are eligible for reimbursement by private insurance companies like Blue Cross or Aetna.

Finally, there are several more ways for FDA pharmaceutical whistleblowers to earn an award and stop fraudulent conduct. These include PAY to DELAY, KICKBACKS, and OFF LABEL MARKETING. These schemes are not included in this eBook. (As future eBooks are published on these topics, they will be linked on this page.)

More Questions About FDA Pharma Whistleblowers?

If you have further questions about becoming an FDA Pharma Whistleblower, whistleblower rights, employer retaliation, or other concerns, please call Halperin Bikel at 929.290.1266 or fill out the confidential contact form at uswhistleblowerlawyer.com. We are happy to help and work diligently to protect your privacy.

About Halperin Bikel PLLC

Representing New York Whistleblowers in New York and throughout the United States

Whistleblowers, perhaps more than anyone else, need an experienced attorney to protect and advocate their rights, from retaliation protection through stopping fraud and maximizing government rewards.

We hope you find this information helpful. If you are considering becoming a whistleblower or have questions about any of the several programs or about your information or job please call our attorneys at Halperin Bikel at 929.290.1266.

Our subject matter experts, and legal team will help you evaluate your circumstances from every side so you will have the best information on your risks and opportunities.

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