

## Prosecutorial discretion

Former federal prosecutor Geoffrey Kaiser explains what influences who gets charged and how

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The recent indictment of USPlabs by the Department of Justice (DOJ) for multiple crimes, including violations of the misbranding and adulteration provisions of the Federal Food, Drug & Cosmetic Act (FDCA), should be a warning to the dietary supplement industry that DOJ is willing and able to pursue criminal charges under the FDCA and other laws.

But it's also a good example of prosecutorial discretion.

Deciding which case merits criminal prosecution, as opposed to merely civil enforcement, is performed on a case-by-case basis. There are, however, certain common factors that will typically guide DOJ's exercise of discretion.

As a general matter, any decision by DOJ to prosecute is guided by the "Principles of Federal Prosecution" from the United States Attorney's Manual (USAM), which provides general guidance.

*The attorney for the government should commence or recommend Federal prosecution if he/she believes that the person's conduct constitutes a Federal offense and that the admissible evidence will probably be sufficient to obtain and sustain a conviction, unless, in his/her judgment, prosecution should be declined because:*

1. *No substantial Federal interest would be served by prosecution;*
2. *The person is subject to effective prosecution in another jurisdiction; or*
3. *There exists an adequate non-criminal alternative to prosecution.*

Layered on top of these principles are the USAM's "Principles of Federal Prosecution of Business Organizations." Factors to consider in making a charging decision against a corporation under these Principles include:

- The nature and seriousness of the offense, including the risk of harm to the public, and applicable policies and priorities, if any, governing the prosecution of corporations for particular categories of crime
- the pervasiveness of wrongdoing within the corporation, including the complicity in, or the condoning of, the wrongdoing by corporate management
- the corporation's history of similar misconduct, including prior criminal, civil, and regulatory enforcement actions against it
- the corporation's timely and voluntary disclosure of wrongdoing and its willingness to cooperate in the investigation of its agents
- the existence and effectiveness of the corporation's pre-existing compliance program
- the corporation's remedial actions, including any efforts to implement an effective corporate compliance program or to improve an existing one, to replace respon-

### NBJ Takeaways

- Set criteria helps federal prosecutors decide which cases to pursue
- How companies cooperate with investigators can affect that decision
- Every case is different and some factors carry more weight than others

sible management, to discipline or terminate wrongdoers, to pay restitution, and to cooperate with the relevant government agencies

•collateral consequences, including whether there is disproportionate harm to shareholders, pension holders, employees, and others not proven personally culpable, as well as impact on the public arising from the prosecution

•the adequacy of the prosecution of individuals responsible for the corporation's malfeasance; and the adequacy of remedies such as civil or regulatory enforcement actions.

The above factors illustrate the kinds of considerations that inform prosecutorial discretion. In general, no single factor will rule out prosecution and some factors may

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not even be relevant in particular cases. Yet, in other cases, one factor could be so important as to dictate whether charges are filed. For example, the USAM holds that

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“nature and seriousness” of the conduct and “the risk of harm to the public” will always be primary factors in deciding whether to charge a corporation.

The USPlabs indictment contains factual allegations that push a number of buttons that tend to encourage prosecutors to bring criminal charges. The case involved alleged fraudulent marketing of dietary supplements that incorporated dangerous ingredients, including a synthetic stimulant known as DMAA, and other ingredients that, as alleged in the indictment, were imported from China under false pretenses utilizing false documentation. Prosecutors maintain the ingredients posed serious safety risks when consumed as intended. As alleged in the indictment, the case involved an “unmistakable course of conduct where, starting at least with DMAA, [USPlabs and its principals] imported numerous shipments of substances intended for human consumption using false and fraudulent [Certificates of Analysis], and other false and fraudulent documentation and labeling.” The indictment further alleges that defendants misrepresented the synthetic ingredients in their dietary supplements as “natural extracts” for marketing purposes and to avoid FDA scrutiny, and recklessly marketed their products knowing that they posed serious health risks, including liver toxicity. The indictment also alleges that defendants generated “hundreds of millions of dollars in sales” from their fraudulent marketing efforts.

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leged, the case involved a widespread national fraud scheme generating hundreds of millions of dollars, posing serious risks to the public health and involving the direct participation of the principals of USPlabs, whose conduct reflected not only a calculated scheme to defraud the public and obstruct FDA’s regulatory authority, but also a callous disregard for the public health consequences of their criminal conduct. In

situations like the USPlabs case, the combination of serious allegations and the USAM charging considerations will frequently favor prosecuting both the business organization and the individuals running that organization.

As noted earlier, however, every case is different, and must be considered. For example, if in another case there were fewer aggravating circumstances present, and there were other mitigating factors—extensive corporate cooperation in the government’s investigation and/or severe and unwanted collateral consequences that could result from prosecution—a different charging decision could be made and still be consistent with the federal charging guidelines described above.

When it comes to the appropriate exercise of prosecutorial discretion in initiating a criminal prosecution under the FDCA, or under any federal criminal statute for that matter, it is never “one size fits all.”

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## USPlabs speaks up

### USPlabs claims evidence suggests their products were not responsible for injuries and deaths reported in the press:

- >> The March edition of Armed Forces Health Surveillance Center’s Medical Surveillance Monthly Report includes an article on heat injuries in the military. An attorney for the company claims that Private Michael Sparling’s death (tied to USPlab’s Jack3D DMAA supplement in a lawsuit and media reports) meets the heat injury criteria noted in the report and that heat injuries were common in the summer of 2011 when Sparling died.
- >> An analysis in the Annals of Hepatology states that authorities were wrong in attributing liver disease cases in Hawaii in 2013 to USPlabs’ OxyElite Pro. The analysis states “It turned out that previous regulatory statements on the cluster cases resulted from biased clinical conclusions, based on invalid and impartial work.”