

United States Senate

WASHINGTON, DC 20510

May 19, 2015

The Honorable Loretta Lynch
Attorney General
United States Department of Justice
950 Pennsylvania Avenue, N.W.
Washington, D.C. 20001

Dear Attorney General Lynch:

Congratulations again on your recent appointment as the United States Attorney General. Undoubtedly there are many issues competing for your time. We write to bring to your attention an important issue affecting the safety and health of the American public.

We are deeply concerned about entities – both individuals and companies – engaging in blatant criminal activity by manufacturing and marketing products that masquerade as “dietary supplements” but contain anabolic steroids, active pharmaceutical ingredients (APIs), or analogues of APIs. These illegal products constitute a serious public health risk. Therefore, we strongly urge DOJ, in cooperation with the Food and Drug Administration (FDA), to prioritize the aggressive pursuit of individuals and companies that illegally manufacture and sell misbranded drug products falsely labeled as dietary supplements. Such an approach would both incapacitate current criminal endeavors and deter new criminality.

FDA has identified some 400 such products over the past six years, including some marketed for bodybuilding, that illegally contain anabolic steroids. Undeclared APIs or their analogues have also been detected in other products marketed with weight loss or sexual enhancement claims.¹ Unfortunately, DOJ’s inconsistent use of enforcement actions against the entities the FDA has identified as manufacturers of these illegal products has weakened the deterrent effect of such actions. By selling adulterated products under the guise of legitimate dietary supplements, these bad actors hijack the credibility of reputable industry members and erode consumer trust in legitimate products. Consumers deserve to have confidence that their dietary supplements contain only legal ingredients properly disclosed on the label. Accordingly, it is imperative that DOJ and FDA use all available tools to hold transgressors fully accountable for their actions.

When FDA determines that a product labeled as a dietary supplement contains an anabolic steroid, an API, or an API analogue, the agency typically issues a warning letter to the firm marketing or manufacturing the product and then works to remove the product from commerce by means of a voluntary recall. While this strategy is an important first step with respect to public health, it does not sufficiently deter bad actors from engaging in this sort of behavior again. Indeed, some of these criminal enterprises simply move on to another illegal ingredient or to a new product brand utilizing the same illegal ingredients. Thus, FDA’s issuance of warning

¹ One industry association maintains a database of products in receipt of a warning letter from FDA where such products have been shown to contain an illegal ingredient. It is available at: www.keepsupplementsclean.org.

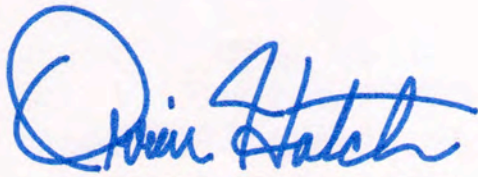
letters and prohibiting the sale of a particular product, without DOJ taking subsequent punitive actions against the entity producing the product, are not enough to sufficiently deter criminal activity.

We applaud the positive results that have come on the occasions that DOJ and FDA have jointly pursued criminal cases of this nature, especially those that have led to successful convictions.² We note, however, that the low number of such criminal convictions has had a limited impact on deterring would-be criminals. Much more could be done. Illicit behavior that puts the public health at risk warrants a full criminal investigation, and if appropriate, criminal charges should be aggressively pursued to punish wrongdoers appropriately while deterring those contemplating engaging in similar conduct.

Not all violations will be felonies, however, and therefore we would like to highlight that the Federal Food, Drug & Cosmetic Act (FFDCA) provides strict liability misdemeanor violations. In addition to pursuing felony convictions where appropriate, we recommend increased utilization of misdemeanor prosecutions as part of a focused-deterrence and selective targeting strategy against current and would-be transgressors. This approach would enable DOJ to proactively hold offenders accountable for their actions within the confines of existing resources.

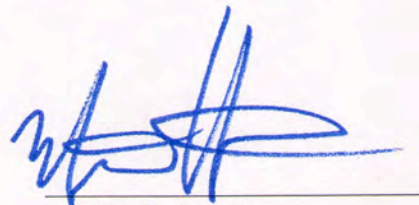
Given our concerns about this serious matter, we ask that you detail how DOJ plans to deploy a forward-thinking regulatory and enforcement strategy to address this public health concern. Also, to the extent possible and consistent with ongoing investigations, we request an update on the Department's investigation into all matters of this nature. Please provide your response by June 30, 2015. Should you have any questions, please contact either Matthew Richardson (Matthew_Richardson@hatch.senate.gov) or Louis Agnello (Louis_Agnello@heinrich.senate.gov).

Thank you in advance for your consideration of this request. We look forward to your response.



Orrin G. Hatch
U.S. Senator

Sincerely,



Martin Heinrich
U.S. Senator

CC: FDA Acting Director Stephen Ostroff

² For example, a nine year prison sentence was announced on April 1, 2015 for a conviction for misbranding involving erectile dysfunction drugs that were mislabeled as dietary supplements (see US Attorney's Office, Western District of North Carolina (www.justice.gov/usao-wdnc/pr/maker-erectile-dysfunction-products-sentenced-nine-years-prison-misbranding-and-selling)). On April 15, defendants entered a guilty plea in a case of misbranding prescription weight loss drugs, also falsely labeled as supplements, and containing drug ingredients that have been removed from the U.S. market by FDA due to safety concerns (see US Attorney's Office, Middle District of Pennsylvania (www.justice.gov/usao-mdpa/pr/owner-harrisburg-diet-supplement-business-charged-selling-misbranded-drugs)).