AMERICAN KRATOM ASSOCIATION

LEGISLATIVE UPDATE

July 19, 2018 Mac Haddow, Senior Fellow on Public Policy

The major focus of our legislative efforts this week on Capitol Hill has been to educate Members and staff on the difference between the natural leaf kratom, that science studies have proven to be safe for use by consumers, and the products that the FDA continues to cite as kratom that are actually products marketed as kratom that are adulterated or deliberately spiked with dangerous opioids and other substances.

This issue is critically important to our efforts to maintain the legality of kratom because the FDA has continued its campaign to demonize kratom despite the growing scientific evidence that their claims about deaths and adverse events "associated" with the use of kratom are wrong. The recently released Hemby study published in *Addiction Biology* sent shock waves through the FDA corridors with the finding that mitragynine, the major alkaloid in kratom, "does not have an abuse potential and reduces morphine intake" which is exactly the pharmacologic activity for "candidate pharmacotherapies for opiate addiction and withdrawal."

This study directly challenges the premise the FDA has advanced in its recommendation for the DEA to schedule kratom, namely that kratom has a high addiction profile and poses a risk to the public health. FDA Commissioner Gottlieb has been critical of kratom on the now clearly discredited claim that kratom has "similar effects to narcotics like opioids, and carries similar risks of abuse, addiction, and in some cases, death."[1]

The FDA now has shifted its attack on kratom to focus on the effects of the other active alkaloid in kratom, 7-hydroxymitragynine (7-OH), and they are telling staff and Members on Capitol Hill that is the reason kratom has to be banned. But the Hemby study makes it very clear that 7-OH is dangerous in purified extracts that enhance the "euphoric effect" and that the danger posed to consumers is by "adulteration or the presence of high concentrations of 7-OH in commercially available kratom products."

What is most important is the FDA itself acknowledges that 7-OH occurs in very low levels in the natural kratom plant – almost undetectable without sophisticated analytical equipment – and if that is truly their concern then they should focus their regulatory and policy tools on adulterated kratom products that deliberately increase the 7-OH levels.

[1] Statement by FDA Commissioner Scott Gottlieb, November 14, 2017.

What the FDA is not telling is they currently have the statutory authority granted by Congress to interdict, seize, destroy, and recall any kratom product that contains a concentrated or artificially elevated level of 7-OH in the product.

STATUS OF SITSA AND HR-6, THE PATIENT AND COMMUNITIES ACT [*UPDATED WITH NEW INFORMATION PROVIDED BY REPRESENTATIVES OF THE KRATOM TRADE ASSOCIATION ON THEIR INACCURATE SOCIAL MEDIA POSTS*]

Unfortunately, a social media posting from the Kratom Trade Association (KTA), based largely on a false news report from Bloomberg News Services, incorrectly claimed that the U.S. Senate had "unanimously cleared their own packages of bills to move forward." This kind of false news reporting occurs occasionally in Washington, and when AKA heard about it, we consulted with other members of the Kratom Federal Lobbying team and quickly were able to confirm with trusted congressional contacts on Capitol Hill that the Bloomberg report was untrue.

However, the incorrect KTA social media posting resulted in numerous calls to Capitol Hill from kratom advocates that forced many Congressional offices to deny the reports. We work hard to build credibility on Capitol Hill and, frankly, this communication damaged our credibility.

Adding to the confusion, and creating even more havoc, was the false claim made by the KTA spokesperson that the SITSA bill "doesn't technically exist anymore now that the Senate created its own package of bills." That statement is completely inaccurate, and no one in the kratom community should be under any illusion that SITSA is no longer a threat to us. It is and will remain a significant threat to kratom until we are able to successfully amend SITSA to specifically exclude natural botanicals and herbs from the broad authority this bill provides to the Attorney General to schedule any substance deemed to pose a public threat.

KTA officials responsible for the social media posts have acknowledged that the content of these posts were mistakes that will not be replicated again. The process of verifying information and assuring accurate social media posting needs to be improved because this episode damaged the kratom community's credibility on Capitol Hill, and it alarmed the grassroots kratom community unnecessarily. Grassroots advocates are encouraged to rely only on trusted sources for information and focus on engaging in outreach to elected officials when specific actions are recommended and endorsed specifically by the advocacy organizations.

This misinformation is very similar to the confusion created during the House deliberations on SITSA where a then newly-formed kratom advocacy group argued in support of SITSA under the claim its provisions would not apply to kratom. That group was completely wrong, but it led to the House Judiciary Committee passing SITSA without the needed amendment. These incidents are self-inflicted wounds that hurt, and they do not help in any way.

At a Kratom Briefing Presentation sponsored by AKA at the CHAMPS Trade Show in Las Vegas, videos of which are on social media, I spoke candidly about the frustration of having to deal with kratom advocates shooting ourselves in the foot. My comments were strong, and I intended them to be.

The KTA spokesperson whose name was on the social media posts has asked me to retract those statements. **I will not do so**.

I was also asked to explain that the posts were authored by several members of the KTA staff, not just the named spokesperson who published them, and that the mistakes were based on an inaccurate report from a respected news outlet in Washington, D.C. That is only a partial explanation at best. First, the postings

contained inaccurate information that was not in the Bloomberg report, and second, KTA fails to explain in any way either why there was no effort to verify the content of that story or explain the description of the Senate action that was not anywhere in that Bloomberg report. In addition, the SITSA posting was explained to be a mistake in a "cut and paste" from another person, and not intended to be posted. But it was.

The kratom community is owed a higher level of integrity in the information circulated, and while mistakes can be made they should not be the result of what is a transparent effort by an advocacy group to be the first to make a report on something that is happening in Washington for the benefit of their group. The utter sloppiness in these multiple postings cannot be explained away by blaming anyone but the group who posted the inaccurate information, and that group alone must be accountable for having done so. I personally believe the organization that person represents must develop controls to assure the dissemination of this kind of grossly mistaken information is not permitted in the future.

The American Kratom Association goes to great lengths to verify information and sometimes is criticized about not releasing information quickly enough. But this is why the AKA has developed credibility on Capitol Hill. Other advocacy groups must be more disciplined and careful to make sure information is accurate and verified. A mistake like this from one advocacy group hurts the entire kratom community.

Adding to the loss of credibility, the FDA had previously announced they are aggressively monitoring social media platforms on any mention of kratom, so they will now have a basis to challenge our advocacy efforts when they make their rounds on Capitol Hill.

What is true about the current status of H.R. 6 is that the U.S. Senate will allow a vote in the near future on the non-controversial sections of the H.R. 6 opioid package. Majority Leader McConnell has asked the HELP and Judiciary Committees to identify any of the provisions where no objections have been raised, and ONLY those provisions will be subject to a vote on the Senate Floor in the near future.

Because of the hard work of the Federal Kratom Lobbying Team, objections have been raised to SITSA, SCREEN, and a number of other provisions where the language is too general and potentially negatively impacts natural botanicals and herbs. We will continue to work to make certain the Committee Chairman know of those objections.

S. 1327, the Senate version of the SITSA Act sponsored by Senator Chuck Grassley (D-IA) and Senator Diane Feinstein (D-CA), is assigned to the Senate Judiciary Committee and is actively being discussed. The SITSA provision in H.R. 6 is also still under consideration.

While I am not much of a social media poster personally, perhaps we need **#accuratekratominformationonly.**

ANNOUNCEMENT OF AKA GMP CERTIFICATION PROGRAM

Congressional staffers are already giving high marks to the announcement yesterday by the AKA to ensure the manufacturing and supply chain of kratom products intended for use by consumers are compliant with FDA regulations and guidelines governing food and dietary supplements. The AKA is committed to protecting consumers, and we will proactively work with kratom vendors to certify compliance with these standards and to protect consumers from any impermissible health claims that mislead consumers. These

standards also clearly demonstrate the kratom community's commitment to safe kratom products, and that greatly increases our credibility with public policy makers at the federal and state levels.

Here are the links to the documents describing this program:

http://files.constantcontact.com/8c72088f601/87ebd9df-cda5-46ad-9097-81f885561c01.pdf

http://files.constantcontact.com/8c72088f601/62a5b810-f67c-4bfc-bc76-96393036b450.pdf

STATE ISSUES

AKA and other advocates will be meeting with Michigan State Senator Jones on July 24 in Lansing Michigan. We understand that Senator Jones is open to reviewing the science and to our discussion about the ways consumers can be protected from adulterated kratom products. A report will be made to you following that meeting.

We are also working hard in preparing for the NCSL Legislative Summit in Los Angeles where more than 1,600 state legislators are gathering to discuss import pubic policies. The AKA will be educating state legislatures about the science supporting keeping kratom legal, and we will brief them on the mistakes being made by the FDA on kratom.