ADDENDUM I

Summary of CSPI research into effectiveness of eight supplements marketed as opioid-dependence supplements

(as of November 22, 2017)

Product	**Cost/ingredients**	**Claims**	**Evidence provided on Web site, marketing, etc.**	**Reply to CSPI email re: evidence of effectiveness**[1]
Mitadone Anti Opiate Aid Plus	$40 a month; 28 vitamins, minerals, botanicals, and other ingredients	"Help Ease Withdrawal Symptoms Associated with use of Oxycontin, Morphine, Oxycodone, Opium, Vicodin, Demerol, Hydrocodone, Lorcet, Methadone, Suboxone, Heroin, Tramadol & other such Painkillers & Opioids. Helps Eliminate Cravings, Symptoms & Helps You Quit"	No evidence offered on website that it makes any difference in opioid dependence https://www.mitadone.com/collections/opiate-withdrawal-aid	"We don't really have any scientific studies as such currently, it takes years & millions of dollars to do that however the product has been working to help ease symptoms for most people that have taken it along with their program, all we can say is proof is in the pudding. Hope the above was helpful. Have a pleasant week. Team Mitadone."
TaperAid Complete	$182 for first month; 17 Chinese herbs	**"**TaperAid Complete helps those individuals who have decided to completely discontinue opioids. TaperAid Complete is used after the last opioid intake. The remedy reduces withdrawal symptoms during the 3-5 day detox period. TaperAid Complete also mitigates post-acute withdrawal symptoms (PAWS) such as insomnia, anxiety, restless leg, and poor appetite. PAWS may continue for up to six weeks."	No evidence offered on website "How many have tried the formula so far? Over 130 people have used TaperAid." https://www.taperaid.com/	"Nope, only informal studies with the 170 people I've shared it with so far. Richard Ogulnick"

Vasovita 2.0	$42 a month; 38 vitamins, minerals, and botanicals	"clinically tested" Website says product was studied in 12 people; no details https://lstisupplements.com/vasovita/	"Vasovita 2.0 is a natural and effective formulation which assists the body's natural functional ability to support individuals who are taking opiates. This formulation has been scientifically developed by a team of scientists and medical doctors to achieve its effectiveness…This was studied in 12 subjects taking Methadone Maintenance Therapy (MMT) who received the adjuvant nutritional formula and compared with 12 controlled MMT subjects not receiving the adjuvant nutritional formula…The favorable support outcome of using adjuvant Vasovita 2.0 is compared with no supportive outcome seen in the control group not receiving the adjuvant Vasovita 2.0 is well detailed in a recent patent disclosure (pending). The findings described above using Vasovita 2.0 as an adjunct to substance abuse treatment apply to MMT treatments and other pain management programs as well.	CSPI Email: "Do you have more information available about your trial…?" Reply: "Thank you for contacting us! Your request has been referred to our scientific team and we will contact you shortly." Response received November 17, 2017: "Thank you for your inquiry about Vasovita 2.0. Yes, we have data documenting highly significant differences between the experimental goup of 6 subjects and the control group of 6 subjects. Because Vasovita 2.0 is currently in a patent pending status, our attorney advises us not to release any further data at this time. We expect patent approval by the end of 2018. Again, thank you for your interest in LSTI and Vasovita 2.0. Sincerely, A. Kenneth Olson, M.D., Ph.D., President, LSTI, LLC

			Patent: https://www.google.com/patents/US5977073	
CalmSupport	$59 a month; 17 vitamins, minerals, and botanicals	"An all natural supplement formulated to help ease the symptoms of opiate withdrawal naturally and effectively" "CalmSupport is one of the leading home remedy withdrawal aids on the market, as well as one of the most affordable…."	No evidence offered on website https://calmsupport.com/	No response to email asking for evidence.
Natracet	$35 a month; five botanicals and 5-HTP (a tryptophan metabolite)	"A dietary supplement that is an all natural, non addictive aid that may help with addiction and withdrawal symptoms…Natracet is 100% legal in all States and we believe is superior to other home remedies."	No evidence offered on website. https://www.natramedicus.com/	No response to email asking for evidence.
Midatrexone Opiate Withdrawal Aid	$40 a month; 11vitamins, minerals, and botanicals	"Ease withdrawal symptoms" "Reduce opioid dependence"	No evidence offered on amazon sales page Appears to be sold only on Amazon https://www.amazon.com/Midatrexone-Withdrawal-Program-Suppressant-Supplements/dp/B074FD9V9V/ref=sr_1_8 Sold by Nu-Derm Products, which also sells beard, breast, and butt enhancement	Evasive answers to several emails, provided in full below.[2] Note: This product no longer appears to be sold on Amazon. But it remains available and sold through ebay upon last search: http://www.ebay.com/itm/like/192360396529?vectorid=229466&lgeo=1&item=192360396529&rmvSB=true (accessed 11/29/17)

			supplements. https://www.marketplacepulse.com/amazon/usa/nu-derm-products	
Opiate Detox Pro	$20 a month; 19 vitamins, minerals, botanicals	"Opioid addiction ease" "Our ingredients are the most effective on the market for treating withdrawal symptoms."	No evidence offered on website. https://www.nutracorehealthproducts.com/product-page/opiate-detox-pro	"Opiate Detox Pro was created by a demand from our Bplex MTHFR customers [this is a B-vitamins supplement for consumers with a genetic mutation that interferes with folate metabolism]. A lot of our customers found that Bplex really helped withdrawal symptoms. So we developed a formula to assist in this process. Withdrawal is a tough market. Everyone is different, but we had to try based on the results. Scientific studies are very costly, so no, there is no study. Detox Pro is certainly not a miracle to withdrawal. Everyone still has symptoms, but what it does do is provide the body with essential nutrients that all users are depleted of. Especially the quatrefolic for the brain, and Methyl B12 for the cells. The body needs this rebuilding process to recover. Hope this helps! Allen Wetmore"
Opiate Freedom Center Ultimate Recovery System	$75 a month; 24 vitamins, minerals, botanicals, and other ingredients	"OFC supplements are formulated to support your body's own natural healing systems, which can in turn ease withdrawal symptoms and shorten detox length. We designed our one-of-a-kind nutraceutical	"carefully researched" but no evidence offered on website https://www.opiate-freedom-center.com/product/opiat	No response to email asking for evidence. Recently referred by the National Advertising Division, an industry self-

		system to specifically supply the critical nutrients most often depleted by addiction to narcotics, prescription opioid painkillers, heroin. Made to help you Ease Withdrawal Symptoms, Shorten Detox Length, Improve Emotional Well-Being, Provide nutritional Support to the Brain During Detox.”	e-withdrawal-recovery-system/	regulatory body, to the FTC regarding its false claims on this product. ‘Opiate Freedom Center’ Fails to Respond to NAD Inquiry, Ad Claims for ‘Detox,’ ‘Withdraw[a]l’ Referred to FTC. The release states: “As part of its ongoing monitoring practice, NAD requested that the advertiser provide substantiation for claims that included: The Ultimate Recovery System: • Three high potency supplements containing a synergistic blend of twenty-three natural vitamins, minerals, herbs and essential amino acids formulated for your mind, body and emotions during detox and withdrawal. Benefits: • Effective At-Home Relief • Promotes Recovery • Speed Your Detox • High Quality Nutrients The Freedom 5-Pack: • “For Those Looking for the Most Complete Natural Supplement Solution Available for a Body & Mind Depleted By Drugs • “Helps You Naturally Replenish Needed Nutrients!” • “The Opiate Freedom Centers all-natural supplements were developed to naturally replenish depleted nutrients

				during opiate detox and withdrawal. It gives you the RIGHT nutrients, in the RIGHT amounts at the RIGHT times.” http://www.asrcreviews.org/opiate-freedom-center-fails-to-respond-to-nad-inquiry-ad-claims-for-detox-withdrawl-referred-to-ftc/

[1] CSPI’s question was: Are there scientific studies showing that [product] works better than a placebo at helping individuals completely discontinue opioids?

[2] The full correspondence was as follows:

- By email through Amazon October 31:Are there scientific studies showing that Midatrexone works better than a placebo to help ease opioid withdrawal symptoms and reduce opioid dependence?
  Reply October 31:Thank you for the email. The clinical data available is on the individual ingredients. This data can be found online. Thanks again
- From CSPI November 1: So the individual ingredients in Midatrexone have been clinically tested for reducing opioid withdrawal symptoms and opioid dependence, but not the product itself?
- Response November 1: Yes, if what you are looking for are randomized, blinded, placebo controlled trials. Those types of trials are usually seen in pharmaceutical products which require them for FDA approval and the supporting studies to demonstrate such efficacy. Midatrezone like the other natural supplements do not fall under that requirement. I hope this helps answer your question and interest. Thanks again. Sal
- CSPI again November 2, 2017: I don't understand your answer. I asked if the individual ingredients in Midatrexone have been clinically tested for reducing opioid withdrawal symptoms and opioid dependence. You responded yes, but then said that Midatrexone like other dietary supplements doesn't require supporting studies to demonstrate efficacy, suggesting that it doesn't have such supporting studies. Even though they're not required, are there scientific studies of Midatrexone's ingredients in opioid-dependent patients and where would I find them? I don't see them in Medline, which indexes more than 27 million medical and scientific citations.
- Response Nov. 2: Yes, if what you are looking for are randomized, blinded, placebo controlled trials. Those types of trials are usually seen in pharmaceutical products which require them for FDA approval and the supporting studies to demonstrate such efficacy. Midatrezone like the other natural supplements do not fall under that requirement. I hope this helps answer your question and interest.
- Another response Nov 2: I appreciate your passion for the topic. Just to clarify. There are no studies. The data available is on the individual ingredients. The reference below is just one example of data available. J Clin Pharm Ther. 2001 Oct;26(5):369-73. Passionflower in the treatment of opiates withdrawal: a double-blind randomized controlled trial. Akhondzadeh S1, Kashani L, Mobaseri

M, Hosseini SH, Nikzad S, Khani M. I understand your need for large amounts of clinical data, and how important this is to you. You may feel more comfortable looking to prescription options since they generally do have large placebo controlled studies. I wish you the best.

Eight Opioid Addiction Dietary Supplements that CSPI Investigated

Note: All are labeled as a "dietary supplement."

One. Mitadone Anti-Opiate Aid Plus Extra Strength

Two. TaperAid

Three. Vasovita 2.0

Four. CalmSupport

Five. NatraCet

Six. Midatrexone Opiate Withdrawal Aid

Seven. Opiate Detox Pro

Eight. Opiate Freedom Center Ultimate Recovery System