Conceive Plus Women's Fertility Support

https://sasmar.com/conceive-plus Sasmar Inc, Chicago Illinois https://sasmar.com/

Contents: 12 vitamins, 7 minerals, and a blend of inositol and the amino acids arginine, cysteine, taurine

Claims made on product labels, Seller's website or Seller's Amazon posting¹

Women Fertility Supplements" (Amazon)

"Dietary supplement formulated for women to get pregnant" (Amazon)

"Take 2 Capsules Daily When Trying To Get Pregnant to Help Boost your Chances of Conception, Naturally!" (Amazon)

"Formulated to provide a complete combination of key fertility vitamins and minerals to help support the body's regulation and specially promote natural fertility for when you are trying to get pregnant!" (Amazon)

"Supports Fertility" (Amazon)

"If you are tired of fertility drugs and their lame promises, we have news for you!" (Amazon)

"If you 've had enough with the harmful side-effects of fertility supplements, now you can sigh in relief! Conceive Plus fertility vitamins help to prepare your body for pregnancy in a safe way, helping you on the patch (sic) to pregnancy, naturally!" (Amazon)

"Only an all-natural dietary supplement is good enough when it comes to fertility ovulation boosting; and we are offering it to you!" (Amazon)

"Conceive Plus Women's Fertility Support is a complete formulation designed for use by trying-to-conceive women" (Amazon)

Questions from CSPI and Verbatim Answers (Conveyed via Amazon message or email, all dates are in 2019)

Q: Are there scientific studies showing that women who take the Conceive Plus dietary supplement are more likely to become pregnant? (emailed via amazon Jan 27)

A: No response.

Q: Are there scientific studies showing that women who take the Conceive Plus dietary supplement are more likely to become pregnant? (emailed to helpdesk@sasmar.com Feb 26)

A: Conceive Plus ® is a trusted brand for couples planning a family.

Developed especially for use by couples who are trying for a baby. Available in bottles of 60 capsules formulated for the requirements of men and women when trying-to-conceive.

Fertility support is essential when trying to conceive, so we recommend using both Conceive Plus Fertility Lubricant and Conceive Plus Fertility Support Multivitamins to increase the chances of getting pregnant naturally.

KEY BENEFITS:

- -Clinically Tested Fertility Friendly
- -Mimics Natural Fertile Fluids
- -Supports Sperm Viability
- -Provides Additional Moisture
- -Calcium & Magnesium Ions
- -Patented Formula

For more information, visit http://www.conceiveplus.com/what-is-conceive-plus

Kind regards,

[Name Redacted]

Front Office Representative

SASMAR PHARMACEUTICALS - Chaussée de La Hulpe 187 Brussels 1170 Belgium

Q: Thank you for your response. But your response and the link you provided to a page on your website don't answer my question. Are there studies showing that women who take the Conceive Plus dietary supplement are more likely to become pregnant? (emailed to sasmar.com Feb 27)

¹ Websites last visited September 2 and 4, 2019. Customer statements were included only if the seller incorporated the quote as a testimonial on their website or Amazon product listing.

Conception

https://store.eunatural.com/collections/supplements/products/conception-female-fertility-prenatal

Eu Natural Inc, San Jose, California https://eunatural.com/

Contents: 8 vitamins, 6 minerals, and a blend of myo-inositol, 4 botanicals (chaste tree berry extract, ashwaganda extract, shatavari root extract, stinging nettle root extract), para-aminobenzoic acid, choline, and BioPerine Nutrient Enhancer

Claims made on product labels, Seller's website or Seller's Amazon posting:

"Taken to promote healthy fertility" (label)

"CONCEPTION by Eu Natural is the one forumula for fertility health and conception, the natural way" (website and Amazon)

"healthy natural fertility aid" (website)

"Do you enjoy the fertility roller coaster? Inconsistent cycles, occasional pain, ovulation quality. The solution is a right mix of full-spectrum fertility supporting extracts, time-tested to promote healthy conception." (website)

"Your search for "the ONE" perfect fertility aid solution is finally over!" (website and Amazon)

"Health-related claims are based upon the collection of ingredient cited studies with notations combined with anecdotal testimonials" (website)

"Fertility Boost" (Amazon)

"improves ovulatory performance when taken daily." (Amazon)

"Conception is our best-selling formula for couples trying to get pregnant. It is a highly effective supplement" (video on website)

Questions from CSPI and Verbatim Answers (Conveyed via Amazon message or email, all dates are in 2019)

Q: A video called "Trying to Conceive" on your Conception website mentions a scientific study in more than 3,600 women that found myo-inositol takers had an improved rate of pregnancy. But the page on Research doesn't list the study. Where can I find this study? (emailed via amazon Jan 14)

A: "... do a search for this paper, Myoinositol as a Safe and Alternative Approach in the Treatment of Infertile PCOS Women: A German Observational Study"

Q: I found the study you mentioned. But it's an observational study without any control group, so it's impossible to say whether the women taking myo-inositol were more likely to become pregnant than if they weren't taking it. I see that two recent meta-analyses of the best studies available concluded that myo-inositol did not increase the chances of becoming pregnant. Is it possible that myo-inositol may improve ovarian function without increasing the likelihood of becoming pregnant? (emailed via amazon Jan 30)

A: No response

Q: Is there evidence that women taking Conception are more likely to become pregnant? Where can I find it? (emailed via company website Feb 26)

A: You can read the reviews that our customers posted on Amazon: https://www.amazon.com/dp/Bo13RMKCV4

Conflam-Forte

https://fertilitysupplementstore.com/product/conflam-forte/

Fertility Nutraceuticals LLC, New York, New York https://fertilitynutraceuticals.com/

Contents: 3 vitamins, alpha-lipoic acid, resveratrol, quercetin, lycopene, curcumin, and 3 botanicals (black pepper extract, ginger root extract, green tea extract

Claims made on product labels, Seller's website or Seller's Amazon posting:

- "Improve your pregnancy chances and reduce miscarriage risks" (website)
- "Improves pregnancy chances with or without IVF and reduces the risk of miscarriages" (website and amazon)
- "improves female fertility by calming a hyperactive immune system and creating a favorable environment for conception and pregnancy" (website)
- "Improve IVF pregnancy chances" (website)
- "Reduce miscarriage risks" (website)"
- "Maintains a healthy pregnancy to term" (website)
- "Calming the inflammatory process can significantly improve a woman's fertility prospects" (website)
- "Since excessive inflammation is very frequent, CONFLAM-Forte™ may be suitable for almost all women preparing for pregnancy" (website)
- "Especially recommended for: Women with PCOS and/or obesity, Women with infertility (website)

Questions from CSPI and Verbatim Answers (Conveyed via Amazon message or email, all dates are in 2019)

- Q: Can you refer me to studies showing that women taking Conflam-Forte are more likely to become pregnant and less likely to miscarry? (emailed via amazon Feb 2)
- A: No response
- Q: Your website says that Conflam-Forte can "improve your pregnancy chances and reduce miscarriage risks." Can you refer me to studies showing that women taking Conflam-Forte are more likely to become pregnant and less likely to miscarry? (emailed to info@fertilitynutraceuticals.com May 1)
- A: No response
- Q: Your website says that Conflam-Forte can "improve your pregnancy chances and reduce miscarriage risks." Can you refer me to studies showing that women taking Conflam-Forte are more likely to become pregnant and less likely to miscarry? (sent via Contact page at https://fertilitynutraceuticals.com/contact/ May 15)
 A: No response

CoQ10

https://www.fairhavenhealth.com/cog10-fertility

Fairhaven Health, New York, New York

Contents: Coenzyme Q10

Claims made on product labels, Seller's website or Seller's Amazon posting:

"Experts theorize that the powerful energy producing activity of CoQ10 is the mechanism by which this ingredient benefits female fertility" (website)

"I have been taking this for about two months. This may sound crazy but I had implantation failure. This was happy news due to the Dr. telling my eggs would never produce any signs at all of being produced. I know it's because of the COQ10. At least now I know it is possible at the age of 51." (website testimonial)

"We have tried to conceive in the past few years and no success. However, after trying the products I can tell a difference in my cycle and ovulation. In my younger days my cycle was 31 days and for the past 4 years it was 27-28 days. Yes, I calender EVERY month. After being on Q10 for the past month my cycle has returned to 31 days exactly! AM arrival like always....awesome! I was sad at 1st because I was hopeful we had conceived but after calming down and thinking about it, I believe our big fat positive results are on the way soon! I am very excited and hopeful. I hope going from a 28 day cycle to 31 days isn't negative in chances of conceiving. I am still on Q10 so we will see what the future holds." (website testimonial)

Questions from CSPI and Verbatim Answers (Conveyed via Amazon message or email, all dates are in 2019)

Q: What is the citation for this study? "A study published in the Journal of Fertility and Sterility found that older women taking up to 600 mg of CoQ10 daily experienced an improvement in both egg quality and subsequent fertilization rates." https://www.fairhavenhealth.com/coq10-fertility I've searched the Journal of Fertility and Sterility, as well as PubMed, and don't find it. (emailed to Fairhaven Health May 23)

A: I am not able to locate that Journal of Fertility and Sterility reference either. I will remove it from the website. Thanks for bringing this to our attention. [Note: This claim about 600 mg of CoQ10 improving fertilization rates no longer appears on the Fairhaven health website.]

Q: Is there a study showing that women taking CoQ10 are more likely to become pregnant? (emailed to Fairhaven Health June 17)

A: With the exception of FertilAid for Men and FH PRO for Men we do not have results from clinical trials on our specific formulations...Like all other US manufacturers of dietary supplements in this fertility space (and in other arenas, I suspect), we are relying on data from research performed on individual ingredients, while at the same time investing in clinical research on several of our products....

D-Chiro Inositol

https://www.amazon.com/D-Chiro-Inositol-Capsules-Vegetarian-Fertility-Reproductive/dp/Bo1N232VFS/

Zazzee Naturals, Valley Cottage, New York

Note: No Zazzee company website. Dexterity Health, LLC, owns the Zazzee trademark. No address or website.

Contents: D-Chiro-Inositol

Claims made on product labels, Seller's website or Seller's Amazon posting:

"Each capsule provides 50 mg of D-Chiro-Inositol, which numerous clinical studies have shown to be the ideal dosage for fertility and reproductive support" (Amazon)

"WIDELY USED FOR FERTILITY: D-Chiro-Inositol, taken with Myo-Inositol, has become the treatment of choice for many fertility-related issues. D-Chiro-Inositol helps to lower elevated blood insulin levels, which more and more research is showing to be the cause of PCOS." (Amazon)

"clinically proven to be the most effective Inositol treatment for fertility support" (Amazon)

"Numerous clinical studies have shown that fertility issues are treated most effectively with a combination of Myo-Inositol and D-Chiro-Inositol" (Amazon)

Questions from CSPI and Verbatim Answers (Conveyed via Amazon message or email, all dates are in 2019)

Q: Is there a study showing that women taking D-Chiro-Inositol are more likely to become pregnant? (emailed via amazon Jan 17)

A: "There are lots of studies and literature showing that Myo-Inositol promotes fertility....There is not, to my knowledge, research supporting taking D-Chiro-Inositol alone to treat fertility, both because D-Chiro-Inositol is much more expensive than Myo-Inositol, and because of the research showing the ideal 40:1 ratio. If you search online for something like "myo-inositol studies fertility", you will quickly find relevant studies showing support for using Myo-Inositol to treat fertility."

Q: Does "promotes fertility" by myo-inositol mean that it increases the likelihood of becoming pregnant? Because that doesn't seem to be clear in the literature. Two recent meta-analyses of the best studies concluded that myo-inositol does not increase the chances of becoming pregnant. Is it possible that myo-inositol improves ovarian function but not the likelihood of becoming pregnant? (emailed via amazon Jan 30)

A: The way I understand it is that Myo-Inositol does not directly promote fertility, but rather, works to improve hormone balance and ovarian function, which, in turn, make it more like to conceive...If you search for an article titled, "A Combined Therapy with Myo-Inositol and D-Chiro-Inositol Improves Endocrine Parameters and Insulin Resistance in PCOS Young Overweight Women", you will find a study supporting the 40:1 ratio. Also, if you search on PCOS support groups, there is a lot of dialog about taking Myo and D-Chiro in this ratio.

Q: But does Zazzee have evidence that myo-inositol even indirectly makes it more likely to conceive? Two recent meta-analyses of the best studies available both concluded that it does not...These two meta-analyses from Spain and Italy found no effect on pregnancy rates: "Inositol supplementation in women with polycystic ovary syndrome undergoing intracytoplasmic sperm injection: a systematic review and meta-analysis of randomized controlled trials." "Myo-inositol supplementation reduces the amount of gonadotropins and length of ovarian stimulation in women undergoing IVF: a systematic review and meta-analysis of randomized controlled trials." To be fair, this recent Chinese meta-analysis did find an effect: "Inositol supplement improves clinical pregnancy rate in infertile women undergoing ovulation induction for ICSI or IVF-ET." This recent Cochrane Collaboration review of the evidence found it "uncertain" whether MI affects pregnancy rate: "Inositol for subfertile women with polycystic ovary syndrome." (emailed via amazon Jan 31)

A: Thanks for sending the titles of the studies. I was able to quickly find all 4 studies that you referenced. I sent your email to the manufacturer, based in the US, who seems to know just about everything about everything, for his comments. I'll be in touch as soon as I heard back from him.

O: Did you hear back? What did he say? (emailed via amazon Feb 26)

A: I'm sorry for the delay on this. I just received a long, detailed response from the manufacturer, which I'm forward to you, below. I hope this helps:

D-Chiro Inositol continued

"Regarding the abstract found at [28756130], their point is that Myo supplementation was insufficient to improve oocyte quality specifically in women with PCOS undergoing intracytoplasmic sperm injection (ICSI). Now, we have to consider what ICSI is. It stands for Intracytoplasmic Sperm Injection and it is an in vitro fertilization procedure in which a single sperm cell is injected directly into the cytoplasm of an egg. Since this type of procedure has a limited success rate anyway, it would make sense that Myo supplementation would not make that much of a difference. In addition, the paragraph concludes that future studies of appropriate dose, size and duration of DCI (D-Chiro Inositol) are vital to clarify its role in the management of PCOS. The article does not specify what doses were used in the randomized controlled trials, the size (I suppose they mean strength) of the product and the duration of the trials, all which play a vital role in the product's success....

Regarding the abstract found at [30078122], the purpose of the study is to "evaluate whether oral myo-inositol supplementation (MI) is able to reduce the amount of gonadotropins (GA) and the length of controlled ovarian hyperstimulation (SL) in both Polycystic Ovarian Syndrome (PCOS) and non-PCOS women undergoing in vitro fertilization (IVF)." The customer indicates that the meta-analyses found that Myo-Inositol does not support fertility. However, the conclusion of this abstract says something contrary: "During IVF, MI is effective in both PCOS and non-PCOS women in saving gonadotropins, but reduces efficiently SL only in PCOS women." My understanding is that if Myo-Inositol was effective in helping PCOS and non-PCOS women in saving gonadotropins, and it helped PCOS women reduce SL (Ovarian Hyperstimulation). The way I read this is that Myo Inositol does help fertility. We also have to take into account the doses used and duration of the study.

[Note: There was no significant difference in pregnancy rates between women given myo-inositol and women in the control groups for the 5 studies and meta-analysis of the 5 studies in the above meta-analysis.]

The 3rd abstract ([29245250]), concludes as follows: "Myoinositol supplement increase clinical pregnancy rate in infertile women undergoing ovulation induction for ICSI or IVF-ET. It may improve the quality of embryos, and reduce the unsuitable oocytes and required amount of stimulation drugs." I suppose the customer can argue that one abstract contradicts the other. However, since neither of these abstracts indicate the exact dose(s) and specific duration of the trials, it is difficult to assess why that might appear to be the case.

[Note: Three of the six studies in the 3^{rd} abstract were open-label or observational studies, not randomized controlled trials.]

Finally, regarding the [Cochrane Collaboration review] article, the circumstances point to a similar scenario as outlined above in the first abstract: The author mentions that he/she is uncertain whether MI improves live birth rate or clinical pregnancy rate in subfertile women with PCOS undergoing IVF pre-treatment taking MI compared to standard treatment. The uncertainty of the author due to the evidence (or lack of it) found does not negate the potential efficacy of the product (again, dose and length of study have to be taken into account)."

Female Fertility

https://www.bioterraherbs.com/products/femalefertility

BioTerra Herbs, Irwindale, California https://www.bioterraherbs.com/

Contents: 8 botanicals (Rehmannia, Chinese Peony, Asiatic Dogwood, Chinese Yam, Poria, Astragalus, Codonopsis, and Epimedium)

Claims made on product labels, Seller's website or Seller's Amazon posting:

"Promotes female fertility" (label)

"Our Female... fertility" carefully blended natural herbs to promote female fertility by addressing the causes that disrupt the family planning journey." (website)

"Chinese Peony: Used for painful menstruation and PCOS." (website)

Testimonials on website's product page:

"I have been using this product for two months and found out I am pregnant! We have been trying for a several months I highly recommend it!"

"I am only on my second bottle and found out I am pregnant!"

"I used it for nearly 3 months until I was able to become pregnant. Right now I am 3 months pregnant!!!!"

"I could not be happier! after 3 months of taking this product, I almost felt like giving up but shortly after, I was late and became pregnant!"

Questions from CSPI and Verbatim Answers (Conveyed via Amazon message or email, all dates are in 2019)

Q: Is there a study showing that Female Fertility increases the chances of becoming pregnant? (emailed via amazon Jan 14)

A: "Our products, as stated on them have not been FDA tested. What we have done is extensive research on studies done to the ingredients in our products and the results that they have yield. You can also read some of our customers reviews on Amazon. As with NON FDA approved supplements, result vary. We have had plenty of success stories. If you have any questions regarding our product or company, please visit our web site that goes by the same name. Either BioTerra Herbs or HerbTheory.

Q: I can't find any good studies on any of the ingredients in Female Fertility that shows women who take them are more likely to become pregnant than women who don't take them. Can you refer me to a study you did extensive research on that shows an ingredient in Female Fertility increases the rate of pregnancy compared with not taking the ingredient? (emailed via amazon Jan 30)

A: I will need to speak to somebody here at the company who has knowledge on these ingredients and why they were chosen to be included in the supplement. (Jan 30)

Q: About a month ago, in response to my question asking if you can refer me to good studies on the ingredients in Female Fertility that shows women who take them are more likely to become pregnant than women who don't take them, you responded: I will need to speak to somebody here at the company who has knowledge on these ingredients and why they were chosen to be included in the supplement. I haven't heard back. Were you able to identify any good studies? Thanks (emailed via amazon Feb 27)

A: This is what i was able to come up with. Hopefully this answers your questions.

Q: Several weeks ago, you responded to my question if there are studies showing that women who take Female Fertility are more likely to become pregnant than women who don't take them. You said you would need to speak to somebody at the company who has knowledge about these ingredients and why they were chosen to be included in the supplement. You followed up with a Feb 27 email saying "Hello David, This is what i was able to come up with. Hopefully this answers your questions." But there was nothing else in the email. Whatever you sent didn't make it. Can you resend your response to me at davidschardt (at) gmail.com? (emailed via Amazon March 21)

A: No response

Q: Several weeks ago, you responded to my question if there are studies showing that women who take Female Fertility are more likely to become pregnant than women who don't take them. You said you would need to speak to somebody at the company who has knowledge about these ingredients and why they were chosen to be included in the

Female Fertility continued

supplement. You followed up with a Feb 27 email saying "This is what i was able to come up with. Hopefully this answers your questions." But there was nothing else in the email. Whatever you sent didn't make it. Can you resend your response to me? (sent via gmail to info@sainthoodusa.com, the contact email at BioTerra Herbs Mar 21) A: No response

Q: Someone who answered my question submitted through Amazon about good studies on the ingredients in Female Fertility showing that women who take them are more likely to become pregnant tried to send me an attachment in response, but I didn't get it (Amazon doesn't allow attachments.) I emailed BioTerra Herbs, but got no response. Do you have this information? (emailed to info@herbtheory.com April 22)

FertilAid for Women

https://www.fertilaid.com/

Fairhaven Health, Bellingham, Washington https://www.fairhavenhealth.com/fertilaid-for-women

Contents: 5 vitamins, iron, myo-inositol, coenzyme Q10, selenomethionine and 3 botanicals (maca root powder, chasteberry vitex, tribulis terrestris)

Claims made on product labels, Seller's website or Seller's Amazon posting:

"Fertility Formula" (label)

"Doctor-formulated for Reproductive Wellness" (label)

"A 2-in-1 female fertility pill that includes fertility enhancing nutrients PLUS a preconception vitamin with 100% or more Daily Value of key vitamins, including methylfolate." (website)

"Studies indicate that preconception multivitamin supplementation **in and of itself** may enhance fertility and increase your chances of conception" (website)

"a complete prenatal vitamin with 100% Daily Value of the vitamins and minerals – vitamin D, folic acid, iron, and iodine, among others- that you want to have on board to enhance fertility" (website)

"includes the herbs Vitex and Red Clover Blossom that help to restore hormonal balance and cycle regularity. With more frequent, predictable cycles you will ovulate more often and you will be able to pinpoint ovulation more accurately so that you can be sure to have sex when you are fertile" (website)

"More than 800 customers shared their experience with us in a self-reported, opt-in internet survey... **Over Half** of Survey Participants **Became Pregnant** While Using FertilAid for Women... **1 in Every 3** Survey Participants Diagnosed with Unexplained Infertility Became Pregnant While Using FertilAid for Women... **3 Out of 4** Survey Participants Believe that Taking **FertilAid for Women** Has Had a **Positive Impact** on their Fertility Status" (website and AMazon)

"In Clinical Trials, Women with Fertility Disorders Who Took Chasteberry/Vitex Agnus Castus Got Pregnant More Often Than the Placebo Groups" (website and Amazon)

"One Clinical Trial Reported that 12 of 16 Previously Infertile Women Were Able to Get Pregnant after Supplementing with PABA over Several Months" (website)

"In a Preliminary Human Trial, Infertile Couples Given Vitamin E (a Key Antioxidant) Showed a Significant Increase in Fertility" (website)

"Learn about FertilAid vs. Fertility Drugs" (broken link on website)

"Learn about FertilAid and PCOS" (broken link on website)

"Ideal for women with irregular cycles and couples who have been trying to conceive for an extended period of time." (Amazon)

"Chasteberry (Vitex) and Red Clover Herbs Have Been Clinically Studied and Validated to Enhance Fertility" (Amazon)

"Many women with PCOS find that taking FertilAid for Women supports cycle regularity and hormone balance, and many of these women choose to combine FertilAid for Women with other Fairhaven Health products that contain myoinositol, such as OvaBoost and Myo-Folate. Or, if you are looking for non-herbal support for PCOS, try FH PRO for Women, which contains myo-inositol and d-chiro inositol." (Amazon)

"This product helped me get pregnant the fist cycle i started using it. After a year of trying this is the last little push i needed. Baby dust to you all!!" (Website testimonial)

"**Tasha** - I struggled to become pregnant for 8 years and so when I heard about this product I gave it a try because it is natural. I started the bottle as instructed and the next month I was pregnant with my daughter. 5 years later I'm ready to try again.

Fairhaven Health Admin - Wonderful to hear of your past success with FertilAid for Women, and we hope you experience the same this time around. Please keep us posted!" (Website testimonial)

Questions from CSPI and Verbatim Answers (Conveyed via Amazon message or email, all dates are in 2019)

FertilAid for Women continued

Q: Are there clinical studies showing that women taking FertilAid for Women are more likely to become pregnant? Also, I noticed that the article "Myo-inositol: A Fertility Tool for PCOS and Beyond" by Dr Chris Meletis doesn't mention two recent systematic reviews/meta-analyses that found that taking myo-inositol did not increase the likelihood of becoming pregnant for women with PCOS or women undergoing IVF. Is there a reason these studies were not included in the article? (emailed to Fairhaven Health Jan 17)

A: The FertilAid for Women and FertileCM formulations are based on available scientific studies showing the role the individual ingredients play in supporting female reproductive health and fertility. Thanks for pointing out the new review papers on myo-inositol. Dr. Meletis wrote his article early in 2018, I believe, so it is likely that the newest studies were not yet published when the article was written.

[Note: The systematic reviews/meta-analyses were published prior to 2018]

Q: You said that the FertilAid for Women and FertileCM formulations are based on available scientific studies showing the role the individual ingredients play in supporting female reproductive health and fertility. I'm trying to figure out what those scientific studies are. On the FertilAid page of the Fairhaven website, it says that "In a Preliminary Human Trial, Infertile Couples Given Vitamin E (a Key Antioxidant) Showed a Significant Increase in Fertility." I can't find that study on PubMed. What study is this? A recent Cochrane Collaboration review concluded that vitamin E was no more effective at increasing fertility than a placebo.

[Fairhaven later replied: "Regarding your question about this statement: "In a Preliminary Human Trial, Infertile Couples Given Vitamin E (a Key Antioxidant) Showed a Significant Increase in Fertility." Thanks for pointing this reference out to us. I'm not able to track down that citation, and my best assumption is that study is related to male fertility, and that this statement should not appear on the FertilAid for Women page. I will research this further and remove that statement if I'm not able to locate the related citation."

The website also says that "Chasteberry (Vitex) and Red Clover Herbs Have Been Clinically Studied and Validated to Enhance Fertility." Recent reviews of Vitex by the Alternative Medicine Review and the American Botanical Council do not support the use of Vitex for enhancing fertility. Also, I don't see any trials of red clover and fertility on PubMed. Can you refer me to the clinically validated studies of Vitex and red clover? Your website says that women with fertility disorders who took chasteberry got pregnant more often. Do you have the references for these studies? (emailed to Fairhaven Health Feb 3)

A: Regarding Vitex and Red Clover: These herbs are included in FertilAid for Women for the purpose of helping to regulate the menstrual cycle and to support hormone balance, which on its own is supportive of fertility. Hormone imbalances can lead to irregular menstruation and/or irregular ovulation, both of which negatively impact a woman's chance of conceiving. Both herbs have a long history of traditional use for gynecological disorders, and there is a small body of clinical research supporting the use for promoting fertility and reproductive health. Specifically related to Vitex, much of the research was conducted in Germany, and is published in German. The studies we cite in support of this herb are listed below. In preparing my response, I did reread the Alternative Medicine Review monograph from 2009 (I can't find a more recent one), and it has a section on Menstrual Cycle Irregularities. Again, if Vitex can help restore hormone balance and regulate a woman's menstrual cycle, that is very helpful for her fertility and chances of becoming and staying pregnant.

Bergmann J, Luft B, Boehmann S, Runnebaum B, Gerhard I. The efficacy of the complex medication Phyto-Hypophyson L in female, hormone-related sterility. A randomized, placebo-controlled clinical double-blind study. Forsch Komplementarmed Klass Natureheilkd 2000; 7(4):190-Abstract on PubMed

[Note: This study tested a homeopathic formulation of Vitex, so its relevance isn't clear.]

Amman W. Favorable effect of Agnus castus (Agnolyt) on amenorrhea. ZFA (Stuttgart). 1982 Feb 10;58(4):228-31. [Note: <u>There's no abstract in this German paper</u>, it cited no references, and doesn't appear to have reported on pregnancies. It used a proprietary extract of Vitex called Agnolyt. Its manufacturer makes no claim about fertility. Fairhaven did not reply about whether FertilAid contains this extract]

Gerhard I I, Patek A, Monga B, Blank A, Gorkow C. <u>Women with fertility disorders benefited from V. agnus-castus obtaining more pregnancies then the placebo group</u>. Forsch Komplementarmed. 1998;5(6):272-278. [Note: This study used a proprietary six-herb formulation called Mastodynon, so it's not really a test of Vitex. The primary outcome, pregnancy among all the subjects, was not significant. The manufacturer of Mastodynon makes no claim about fertility.]

Propping D, Katzorke T. Treatment of corpus luteum insufficiency. Zeitschr Allgemeinmedizin 1987;63:932–3. [Note: This study, which is not on PubMed, was an open, uncontrolled study of 18 women who had been unable to conceive for a period of more than two years. Two women given 40 drops of the proprietary extract Agnolyt daily for three months became pregnant. But without a control, it's impossible to say that Vitex was responsible. Fairhaven did not reply to whether FertilAid contains the same amount of Vitex as Agnolyt.]

Specifically related to Red Clover, I recommend <u>this article by Dr. Chris Meletis</u>, which provides a concise summary of the clinical uses of Red Clover and related research.

[Note: This article offers no evidence that red clover affects fertility.]

And, yes, the 2017 Cochrane Review on antioxidants for female fertility showed that the evidence is mixed. Designing robust clinical trials to assess interventions for female fertility is extremely complicated, so it is not too surprising that the research in this area is not as strong as the research on antioxidants for male fertility. Nevertheless, it is well established that oxidative stress has a negative impact on female fertility, which is why we believe antioxidant supplementation can provide benefit. Here is a review article in which this is discussed: https://www.ncbi.nlm.nih.gov/pubmed/22748101.

[Note: this article concludes that convincing evidence so far is lacking that antioxidant supplementation can help. Here are the final three sentences of the review: "...clinical trials investigating the use of antioxidants to treat reproductive disorders have reported largely conflicting results. Moreover, the bulk of evidence in support of therapeutic effects of antioxidants to date, have been observed through experimental studies on animals or through in vitro studies. In the future, human clinical trials will help to clarify the efficacy of antioxidants as potential therapies for infertility."]

Q: Your website says that a clinical trial found that previously infertile women were able to get pregnant after taking PABA: "One Clinical Trial Reported that 12 of 16 Previously Infertile Women Were Able to Get Pregnant after Supplementing with PABA over Several Months." What is the reference?

A: The citation for the PABA study that we reference is: Sieve BF. The clinical effects of a new B-complex factor, para-aminobenzoic acid, on pigmentation and fertility. South Med Surg 1942(March);104:135–139.

[Note: This was 77-year-old small uncontrolled study of PABA for treatment of infertility and vitiligo in men.]

Q: I assume women buying a "fertility supplement" that claims it has "helped tens of thousands of women to conceive" are looking to become pregnant. So, it seems fair to ask: does taking the supplement really increase the chances of conceiving a child and what's the evidence for that? (emailed to Fairhaven Health March 14)

A: ...we have provided the available research that we believe is supportive of the benefits of this product, and have spoken to the limitations of this research. While this is perhaps unsatisfactory to you, we believe that FertilAid is an effective and safe natural product, established by more than 15 years of it being on the market. Based on your questions, I think that we agree that it would be wonderful to see more double-blinded placebo-controlled trials on natural ingredients for all health conditions, including fertility. I will say that after working in this industry for 20 years, the growing interest in natural interventions has been met with a growth in the amount of research that is being done. I take that as good progress, and I do think we will continue to see more robust research being done. It has also been interesting for me to see that as medical fertility interventions get more sophisticated (IVF, etc), there is an increasing demand for our natural products (and, consequently, research to support them), as the fertility doctors are looking for every advantage for their patients. At Fairhaven Health, we are working with fertility clinics and research partners both here in the US and in other parts of the world to conduct research on our FH PRO for Men and Women products. Here's a link to results of a recent study on FH PRO for Men.

In summary, while we continue to work towards building the body of research to evaluate natural interventions for fertility, I feel strongly that our dietary supplements are a low-cost, effective way to support female fertility. I think I've made this statement before, but to repeat, generally speaking, we believe (with support of clinical research and a large percentage of the medical professionals who work in fertility) that there are interventions that help women and men "increase their fertility naturally", which include improved diet, exercise, maintaining healthy weight, and taking specific dietary supplements. These interventions have the benefit of improving sperm health, egg health, ovulation frequency, and uterine lining, to name a few, which increase fertility and "help increase your chances of conceiving" or, said slightly differently, "help increase your chances of becoming pregnant." This is the story we share with our customers, and, again, I believe this to be a defensible case.

FertileCM

https://www.fairhavenhealth.com/fertilecm

Fairhaven Health, Bellingham, Washington

Contents: Vitamin C, calcium, arginine, N-acetyl-L-cysteine (NAC), Lactobacillus acidophilus, and grape seed extract

Claims made on product labels, Seller's website or Seller's Amazon posting:

"FertileCM is designed to improve both the quantity and quality of a woman's cervical mucus. In addition to mucus production, FertileCM helps to strengthen the uterine lining for better implantation of the embryo." (website)

"Doctor-designed to support the quantity and quality of fertile cervical mucus." (website)

"Fertility Issue #1 - Abundant Fertile Cervical Mucus is a MUST, Not an Option, for TTC" (website and Amazon)

"Fertile cervical mucus during ovulation is central to getting pregnant" (website and Amazon)

"The ingredients in FertileCM promote the production of healthy, fertile-quality cervical secretions" (website and Amazon)

"Fertility Issue #2 – Uterine Lining Not Thick Enough" (website and Amazon)

"L-Arginine, a key ingredient in FertileCM, has been shown to increase endometrial secretions and help strengthen the uterine lining for implantation of a fertilized egg and healthy pregnancy" (website and Amazon)

"Fertility Issue #3 – Low Sexual Libido and Arousal" (website and Amazon)

"FertileCM supports the production of endometrial secretions which in turn: Improve the chances of successful implantation" (website and Amazon)

"Helps the Body Produce Fertile Cervical Mucus" (website and Amazon)

"L-Arginine Is Well Studied and Offers Proven Results. In the Takasaki et al 2010 study of 61 patients, 67% of patients developed endometrium more than 8mm by taking L-Arginine" (website and Amazon)

[Note: This was not a placebo-controlled trial. Nine women -- not 61 -- with endometrial thickness less than 8 mm were given 6 gm of arginine a day for one cycle. That's at least 6 times as much arginine as in FertileCM. Endometrial thickness exceeded 8 mm in 6 of the 9. One of the 9 became pregnant, which was not significantly more than a control group who did receive a treatment or placebo.]

"Effective Doses. Doctor Recommended." (website and Amazon)

"We had been trying to get pregnant for almost a year and had done many medicated cycles. I used this product for the first time last month (and my husband used FertilAid for Men) and got our Positive this month!" (website testimonial)

"Promotes Production of Fertile-Quality Cervical Mucus When Trying to Conceive" (Amazon product page)

"Supports the production of "fertile quality" cervical mucus" (Amazon product page)

"FertileCM can help you overcome these three common reasons for infertility." (Amazon product page)

Questions from CSPI and Verbatim Answers (Conveyed via Amazon message or email, all dates are in 2019)

Q: Are there clinical studies showing that women taking FertilAid for Women or FertileCM are more likely to become pregnant? Also, I noticed that the article "Myo-inositol: A Fertility Tool for PCOS and Beyond" by Dr Chris Meletis doesn't mention two recent systematic reviews/meta-analyses that found that taking myo-inositol did not increase the likelihood of becoming pregnant for women with PCOS or women undergoing IVF. Is there a reason these studies were not included in the article? (emailed to info@fairhavenhealth.com Feb 3)

A: The FertilAid for Women and FertileCM formulations are based on available scientific studies showing the role the individual ingredients play in supporting female reproductive health and fertility. Thanks for pointing out the new review papers on myo-inositol. Dr. Meletis wrote his article early in 2018, I believe, so it is likely that the newest studies were not yet published when the article was written.

[Note: The two meta-analyses were available at the time Dr. Meletis published his article.]

With the exception of FertilAid for Men and FH PRO for Men we do not have results from clinical trials on our specific formulations. FH PRO for Women is currently being used in a clinical trial in an IVF setting looking at fertilization

FertileCM continued

rates, and some other end points, but we do not have data yet. Like all other US manufacturers of dietary supplements in this fertility space (and in other arenas, I suspect), we are relying on data from research performed on individual

ingredients, while at the same time investing in clinical research on several of our products....

Generally speaking, we believe (with support of clinical research and a large percentage of the medical professionals who work in fertility) that there are interventions that help women and men "increase their fertility naturally", which include improved diet, exercise, maintaining healthy weight, and taking specific dietary supplements. These interventions have the benefit of improving sperm health, egg health, ovulation frequency, and uterine lining, to name a few, which increase fertility and "help increase your chances of conceiving" or, said slightly differently, "help increase your chances of becoming pregnant." This is the story we share with our customers, and, again, I believe this to be a defensible case.

FertileDetox

https://www.fertiledetox.com/

Fairhaven Health, Bellingham, Washington

Contents: 9 vitamins, 6 botanicals (citrus pectin, dandelion root, beet root, milk thistle seed, green tea leaf extract, grape seed extract), 5 minerals, 4 probiotics (Lactobacillus acidophilus, Lactobacillus rhamnosus, Bifidobacterium bifidum, Bifidobacterium longum), 3 amino acids (glutamine, glycine, taurine). calcium-d-glucarate and N-acetyl-L-cysteine (NAC)

Claims made on product labels, Seller's website or Seller's Amazon posting:

"promote reproductive health and fertility" (label)

"FertileDetox helps your body remove chemical toxins that can interfere with the healthy development of a growing fetus." (website)

"Fertility Cleanse for Men & Women Before Getting Pregnant" (website)

"Supports gut and liver detoxification to remove toxins that may impact fertility and the development of your baby." (website)

"Set the Stage for Conception" (website)

"Doctor-designed FertileDetox™ was formulated to enhance fertility in women and men" (website)

"Fairhaven Health developed FertileDetox™ in response to mounting scientific evidence linking toxin exposure to decreases in male and female fertility as well as increases in pregnancy complications and birth defects. FertileDetox™ for Men and Women is designed to improve fertility and promote the health of a baby by helping with efficient elimination of environmental toxins from the body" (website)

"Double Your Effectiveness By Detoxing as a Couple. FertileDetox works for both men and women and can be taken before and during trying to conceive as part of a holistic pre-conception regime. No need to do this detox in isolation of improving sperm health or egg quality. When the clock is ticking, it is perfectly natural to want to work on more than one aspect of fertility at the same time" (website)

"FertileDetox for Men and Women is designed to improve fertility" (website)

"Better results than clomid! I honesly was iffy about taking this. I wondered if I was wasting my money. I have two clomid babies. I also own the ovacue monitor and both times I tried using it while taking the clomid and was given vaginal readings that were too high to give. It kept telling me to retest on the monitor. I gave up using it because of this, but was thankful enough to get pregnant using the clomid. Well, I've been taking it for 8 days now and i'm getting amazing readings on my ovacue monitor. This is better than when I took clomid! The readings aren't even crazy high like before if I was able to get one. I'm getting good normal readings! I've never been told to retest or anything. I'm so hopeful!" (Website testimonial)

"Set the Stage for Pregnancy with FertileDetox!" (Amazon)

"FertileDetox Supplement for Women and Men is a gentle detox and cleanse formulated by fertility experts specifically for couples who are trying to conceive" (Amazon)

"Contains Key Ingredients Shown to Mitigate the Negative Effects of Toxins on Your Fertility and Your Baby by Increasing Your Body's Ability to Remove Toxins" (Amazon)

Questions from CSPI and Verbatim Answers (Conveyed via Amazon message or email, all dates are in 2019)

Q: Is there evidence that women taking FertileDetox or its ingredients are more likely to become pregnant? (emailed to Fairhaven Health April 5)

A: I'm happy to continue to answer questions about our products, but the nature of your questions lead me to believe that you are not asking for the sole purpose of becoming an educated consumer of fertility supplements. I noticed a while back that you are contributing author to the Nutrition Action Newsletter. Before I spend too much more time on this, I'd appreciate knowing if you intend to use my responses in any articles. And, if not, I'd appreciate knowing what you intend to do with my responses. Kind regards, Suzanne Munson, VP of Product Development/Compliance, Fairhaven Health (April 8)

Q: Yes, I am that David Schardt. I retired from CSPI and the Nutrition Action Healthletter after 25 years and now work on projects for them. They asked me to explore the basis for claims that companies make for women's fertility supplements. So, I've been asking 30+ companies like Fairhaven what is your evidence that women taking your supplement increase their chances of becoming pregnant. Since many of these companies do not seem to be able to

substantiate their claims, this project will likely end up as some kind of report and perhaps an article in NAH. That hasn't been determined yet, but if this ends up in an article, NAH is a stickler for not misquoting or taking information out of context. How do we intend to use your responses? I don't know. We're not there yet. While Fairhaven has a lot of fertility products, it's only one of several dozen companies selling fertility supplements. I do appreciate that you have answered my questions and hope that you will continue to do so. (May 6)

A. No response.

Q: I realize that you seem to have stopped answering my questions, but I must ask the following: None of the 27 references cited on the website show that women taking the amounts of the ingredients in FertileDetox are more likely to become pregnant. How do we know that FertileDetox actually makes a difference in whether women become pregnant? (emailed to Fairhaven June 17)

A: I'm haven't stopped answering your questions - you've just hit me at an especially busy time...I will review your questions and try to get you a response before I leave for vacation. (June 17)

A: With the exception of FertilAid for Men and FH PRO for Men we do not have results from clinical trials on our specific formulations. FH PRO for Women is currently being used in a clinical trial in an IVF setting looking at fertilization rates, and some other end points, but we do not have data yet. Like all other US manufacturers of dietary supplements in this fertility space (and in other arenas, I suspect), we are relying on data from research performed on individual ingredients, while at the same time investing in clinical research on several of our products....

Generally speaking, we believe (with support of clinical research and a large percentage of the medical professionals who work in fertility) that there are interventions that help women and men "increase their fertility naturally", which include improved diet, exercise, maintaining healthy weight, and taking specific dietary supplements. These interventions have the benefit of improving sperm health, egg health, ovulation frequency, and uterine lining, to name a few, which increase fertility and "help increase your chances of conceiving" or, said slightly differently, "help increase your chances of becoming pregnant." This is the story we share with our customers, and, again, I believe this to be a defensible case. (June 27)

FertileQQ

http://naturalpgg.com/?project=fertilegg-natural-pgg

Extreme V.com, Lewes Delaware https://www.extremev.com/

Contents: Pyrroloquinoline quinone (PQQ) and ubiquinol (Coenzyme Q10)

Claims made on product labels, Seller's website or Seller's Amazon posting:

"Ultra Fertility Formula" (label)

"FertileQQ™ ULTRA is a preconception support formulation that combines the active form of CoQ10 (QH-Ubiquinol) with PQQ (NaturalPQQ™). These two super nutrients are recognized at leading fertility clinics to optimize support of mitochondria egg cell health for women who desire to Get Pregnant Now" (website and Amazon)

"Sufficient PQQ levels in the body may support fertility" (website and Amazon)

"FertileQQ™ supports the mitochondria, our cell's energy centers...Healthy eggs with robust mitochondrial functioning promote ovulation and support conception" (website and Amazon)

"Healthy eggs with robust mitochondrial functioning promote ovulation and support conception" (website and Amazon)

Questions from CSPI and Verbatim Answers (Conveyed via Amazon message or email, all dates are in 2019)

Q: Is there a study showing that taking FertileQQ increases the chances of pregnancy in women? I couldn't find any in the list of 165 references on your website. (emailed to naturalpqq.com Jan 14)

A: No response

Q: Is there a study showing that taking FertileQQ increases the chances of pregnancy in women? I couldn't find any in the list of 165 references on the naturalpqq.com website. (emailed to info@extremev.com. Jan 30)

A: No response

Q: Are there studies showing that women who take FertileQQ are more likely to get pregnant? Where can I find them? (emailed to Amazon seller Azendus Feb 27)

FertileXX

https://www.nativeremedies.com/fertile-xx-support-healthy-ovulation.html

Native Remedies LLC, Boca Raton, Florida/Silver Star Brands, Inc, Oshkosh, Wisconsin https://www.nativeremedies.com/

Contents: 3 botanicals (Chaste tree berry, black cohosh root, eleuthero root)

Claims made on product labels, Seller's website or Seller's Amazon posting:

"Promotes female reproductive health & fertility" (label)

"Promotes fertile conditions in the female body for ovulation and conception" (website)

"Fertile XX is a 100% safe, non-addictive, natural herbal remedy containing a selection of herbs to support fertile conditions for ovulation and conception" (website)

"We have had a variety of testimonials from our customers, some reporting very quick results and others reporting results after 6-12 months" (website)

"Around the world on a daily basis, millions of couples try to conceive. Unfortunately, sometimes this is easier said than done. Some women seem to conceive with ease time and time again, while others may take a little longer than expected." (website)

"No medicine (including herbal medicine) can help if there are severe structural or genetic problems that affect fertility. It is important to know the cause so that you receive the correct treatment." (website)

Testimonials on website's product page:

"I now am trying to conceive so I'm going to order a bottle and see if it does the trick, I'm 45 years old and this would be my first"

"After years of trying to conceive and a failed IVF, I bought your Fertility herbal herbs . The doctor treating me for infertility said I will likely not be able to get pregnant with my own eggs. But I got pregnant for the first time in my life" "I came across the Fertile XX and decided to give it a try. I had been trying 1 year to get pregnant and got nothing but negative results. After 1/2 a bottle we are happy to say I got a positive result!!"

**Note: As of 8/30/19 FertileXX is no longer available on Amazon, except in a combo pack with the male counterpart FertileXY. Link.

"Treat problems making it difficult to get pregnant with both products in one convenient package at a savings of 10%" (Amazon)

"ComboPacks consist of multiple remedies that work well together to provide increased support for your condition" (Amazon)

"promote reproductive health, increase sperm production, regulate ovulation and improve overall systemic health, without the negative side effects of prescription drugs and conventional infertility treatments." (Amazon)

Questions from CSPI and Verbatim Answers (Conveyed via Amazon message or email, all dates are in 2019)

Q: Is there a study showing that taking Fertile XX increases the chances of becoming pregnant? (emailed to service@nativeremedies.com Jan 14)

A: I am sorry, but there have not been any studies showing the success of Fertile XX. We have had comments from customers whom have used the natural remedy after a period of time and becoming pregnant after long lengths of time not having success. Our founders daughter in law used Fertile XX after a long period of time trying to get pregnant. And after about 4 months using Fertile XX she was pregnant. An individual working here has used with success of getting pregnant after using for 5 months. So, there have been positive results with this natural remedy. You do have to keep in mind that natural remedies work differently for everyone. (Jan 14)

FertilHerb for Women

https://www.fertilherb.com/

FertilHerb, New York, New York

FertilHerb® is a registered trademark(™) of SAL NATURE LLC, Buffalo, Wyoming (no website)

Contents: 5 vitamins, iron, myo-inositol, coenzyme Q10, selenomethionine and 3 botanicals (maca root powder, chasteberry vitex, tribulis terrestris)

Claims made on product labels, Seller's website or Seller's Amazon posting:

"Advanced Fertility Formula" (label)

"Best-Selling female fertility supplement" (website)

"Before turning to complex fertility treatments, we suggest you try FertilHerb® for Women and Enhance Your Female Fertility!" (website)

"Irregular or abnormal ovulation accounts for 30% to 40% of all cases of infertility. FertilHerb® for Women is an all natural, fertility-enhancing supplement, specially developed for trying to conceive women who are looking to balance the hormones that govern their monthly cycle." (website and Amazon)

"Natural Fertility Supplement to Improve Female Fertility" (website)

"Science-based Formula" (website)

"FertilHerb® for Women – fertility supplement to promote hormonal balance and help you conceive" (website)

"FertilHerb for women was formulated by leading fertility experts to offer a unique approach to enhancing female fertility (website)

"a proprietary blend of scientifically validated fertility enhancing herbs" (website)

"a perfect natural alternative to fertility drugs or invasive treatments" (website)

"Did you know? About 10% of women in the U.S. Ags 15-44 are infertile

PCOS, also known as the polycystic ovarian syndrome is the most common cause of ovulation problems leading to female infertility. PCOS is a hormone imbalance problem which can interfere with normal ovulation." (PDF linked on website)

Clinical studies cited on website:

- "Regidor and A. E. Schindler. 2016. Myoinositol as a Safe and Alternative Approach in the Treatment of Infertile PCOS Women: A German Observational Study"
- Brown DJ. 1995. Vitex agnus castus. Clinical Monograph. Townsend Letters for Doctors and Patients.
- Bayer R. 1960. Treatment of infertility with vitamin E. Int J Fertil 5:70-8.

"Natural Fertility Supplement Designed to Improve Fertility in Trying to Conceive Women" (Amazon)

"A Natural, Advanced Formula to Promote Hormonal Balance and Conception" (Amazon)

"Irregular or abnormal ovulation accounts for 30% to 40% of all cases of infertility." (Amazon)

"The Perfect Natural Alternative to Fertility Drugs" (Amazon)

Questions from CSPI and Verbatim Answers (Conveyed via Amazon message or email, all dates are in 2019)

Q: Is there a study showing that taking FertilHerb increases the chances of becoming pregnant? (emailed via amazon Jan 14)

A: Seller sent list of dozens of studies, none of which provided credible evidence (Jan 14)

Q: Several weeks ago, in response to my inquiry about the evidence that FertilHerb can increase the chances of a woman becoming pregnant, you sent me a list of 19 references. Eight of the references were studies about men, not women. I've gone through the other 11 references and frankly none of them provide credible evidence that the ingredients in FertilHerb can increase the likelihood of becoming pregnant. Here's what the references showed:

Regidor & Schindler: an uncontrolled observational study; Brown: This Monograph is no longer available from Townsend Letter, but two recent reviews of the evidence on Vitex from the Alternative Medicine Review and the American Botanical Council do not support the use of Vitex for infertility; Mistry et al: Concluded there is inadequate evidence to recommend selenium for infertility; Lerchbaum & Rabe: Didn't look at pregnancy rates; Ben-Meir et al: a

FertilHerb for Women continued

study in mice; Propping et al.: discusses use of chasteberry for infertility, but there was no trial; Caan et al.: Not a clinical study and didn't address ingredients in FertilHerb; Bayer: This is a 60-year-old article from a journal that ceased publication 27 years ago. The most recent review by the Cochrane Collaboration of the clinical research on vitamin E found that it was no more effective than a placebo at increasing pregnancy rates; Rushton et al.: a letter, not a clinical trial; McCloud: discusses possible causes of infertility, not evidence for treatment effectiveness; Czeizel: looked at birth defects, not pregnancy rate.

Is there any other evidence that women taking FertilHerb or its ingredients will increase their chances of becoming pregnant? (emailed via amazon Feb 3)

A: No response

Q: About a month ago, you sent me a list of 19 references in response to my question asking if there are studies showing that women taking FertilHerb are more likely to become pregnant. None of the 19 studies provided credible evidence for an increased rate of pregnancy. Is there any other evidence that women taking FertilHerb or its ingredients will increase their chances of becoming pregnant? (emailed via amazon Feb 27)

A: No response

Q: None of the 11 "clinical studies" on the website provide credible evidence that the ingredients in FertilHerb for Women can increase the likelihood of becoming pregnant. 3 were not studies, 2 were uncontrolled studies, 2 reviews didn't present any evidence for increased pregnancy rates, 2 studies didn't look at pregnancy rates, 1 review concluded the evidence was inadequate, and 1 was an animal study. Do you have other studies showing that FertilHerb for Women can increase the chances of becoming pregnant? (emailed to info@fertilherb.com June 12)

Fertilify

https://fertilify.com/

Fertilify, Toronto, Canada

Contents: 4 vitamins, zinc, coenzyme Q10, Pyrroloquinoline quinone (PQQ), resveratrol, and the amino acid taurine

Claims made on product labels, Seller's website or Seller's Amazon posting:

"Supports fertility when trying to conceive naturally" (label)

"Complementary to fertility treatment or egg banking" (label)

"FERTILIFY for when you are ready" (website)

"OTC, No Prescription Required" (website)

"Fertility Pre-Pregnancy supplement for women" (website)

"It's baby making time!" (website)

"we believe that traditional Prenatal Vitamins, although useful once you become pregnant, don't do enough for you when you're trying" (website)

"FERTILIFY Pre-Pregnancy supports fertility when trying to conceive naturally, and is also complementary to fertility treatment or egg banking" (website)

"We help your baby before it's even conceived, let alone support your chances for a healthy conception" (website)
"Coenzyme Q10 (Ubiquinone)...Supports mitochondrial health, which is important to fertility...There are 8,983 studies

"Coenzyme Q10 (Ubiquinone)...Supports mitochondrial health, which is important to fertility...There are 8,983 studies on CoQ10 and counting" (website)

"Resveratrol...Neutralizes effects from toxins and pollutants that can reduce fertility...There are 10,203 studies on Resveratrol and counting" (website)

"Vitamin E...Supports mitochondrial health, which is important to fertility...There are 45,890 studies on Vitamin E and counting" (website)

""It works! After 3 years of trying I am pregnant!!! Definitely recommend this product" (Website testimonial)

"Highly Recommend!!! Was trying for over a year and nothing took this for less then a month and well surprise!!! I'M PREGNANT!!!! Highly recommend this product!!!" (Website testimonial)

Questions from CSPI and Verbatim Answers (Conveyed via Amazon message or email, all dates are in 2019)

Q: Is there a study showing that taking Fertilify increases the chances of becoming pregnant? (emailed via amazon Jan 14)

A: we leverage 3rd party scientific studies (found in a scientific journal called Fertility and Sterility) on our individual ingredients (CoQ10, antioxidants, methylfolate, etc). Our doctors actually did many of these experiments and wrote those journals. What FERTILIFY does is help support reproductive health, which can help increase your chances of conception. Note that, there are many variables for conception (some that require medical attention), which is why it's always important to understand your fertility health with examinations from your doctor.

Q: I'm having trouble locating these articles in Fertility and Sterility. Could you tell me your doctors' names so I can search for their studies by name? (emailed via amazon Jan 30)

A: Definitely: Dr. Robert Casper is our main doctor/scientist. He's a managing partner at Trio Fertility, and is recognized as one of the leading fertility doctors in the world.

This is a great study: https://www.ncbi.nlm.nih.gov/pubmed/26111777

Q: Thank you for your reply, but this is a study in mice, not women. The authors conclude "While our results in an animal model appear promising, there are tremendous differences between aging mice and women...Additional large-scale studies on dosing, length of treatment, and clinical outcomes safety are necessary before the use of CoQ10 in a clinical setting." Do you have a study showing that taking Fertilify, or the amounts of ingredients found in Fertilify, increases the likelihood of women becoming pregnant? (emailed via amazon Jan 31)

A: The mice model is used with a specific type of lab mouse that is designed to help scientists find solutions for human use... it's extremely rare for supplements (non-drugs) to even get so far as to have an animal based study...Our position is that we are the only supplement that leverages this advanced form of study. Although no human studies are done for fertility, there is anecdotal evidence that supports the claims, and are currently supporting further research efforts. We do know that our ingredients are safe for humans to take daily, that their is advanced animal based evidence, and that our price point is relatively inexpensive, so it's worth it for our customers to use it. As well, based on this level of

Fertilify continued

evidence, we are also recommended by fertility doctors and sold in participating fertility clinics; that helps with your assessment of our diligence....Also note that no drug or supplement can legally claim to get someone pregnant...it's impossible. What is true, and legal, is that a drug or supplement can work to support reproductive health, which is what we do...FERTILIFY is safe, has the support of advanced studies (as far as supplements go), is supported by doctors that practice fertility (it's formulated by fertility doctors), is fairly inexpensive, and lastly...it's available now.

Q: I won't belabor the point, except to point out that there has been a recent study of CoQ10 in women with ovarian issues in which CoQ10 failed to significantly increase the pregnancy rate. Reprod Biol Endocrinol. 2018 Mar 27;16(1):29. (emailed via amazon Jan 31)

A: We welcome the intrigue! A big part of fertility health is education, and we encourage our customers (and potential customers) to do learn as much as they can. About your study example, CoQ10 isn't a panacea for fertility, but there's a lot of evidence (and growing) that shows it can help in a very specific way. CoQ10 actually works to remove ROS (Reactive Oxygen Species) right at the mitochondria, where it is produced as a byproduct of cellular respiration (and can be over produced from pollution, poor diet, stress, aging, etc). ROS causes point mutations in mitochondrial DNA, making the mitochondria weaker (can't make as much energy) which is a huge issue for fertility as egg cells have the most mitochondria in the body (120x more than even heart muscle cells). So, if there is some other more specific ovarian issue which the study you mentioned may have), it might not help that specificity. We designed our products to cover as much as possible for a supplement, within health regulatory guidelines to be safe and over the counter, no prescription required. Hopefully, you found this chat helpful. Best of luck!

Fertility

https://pinkstork.com/product/fertility-supplement-bundle/

Pink Stork, St. Augustine Beach, Florida https://pinkstork.com/

Contents: 10 vitamins, 6 minerals, myo-inositol, D-chiro inositol, coenzyme Q10, choline, para-amino benzoic acid (PABA), and 5 botanicals (chaste tree berry extract, black pepper fruit extract, shatavari root extract, stinging nettle leaf, ashwagandha root extract)

Claims made on product labels, Seller's website or Seller's Amazon posting:

"an exclusive blend of vitamins and extracts that are recommended to optimize fertility" (label)

"safe, healthy, & effective fertility support" (label)

"pretty much every vitamin and herb that is recommended to support fertility" (website)

"We want to get you on the path to a healthy, joyous pregnancy" (website)

"Symptoms: Fertility, Inconsistent Cycles, Hormones"

"it's going to boost your fertility" (video on Amazon product page)

"the natural, non-invasive fertility support you've been waiting for" (Amazon)

"Pink Stork Fertility isn't an ordinary fertility aid – it also provides complete prenatal nutrition for a woman." (Amazon) "Our incredible fertility boosting formula is safe for all women and scientifically backed with decades of research"

(Amazon)

Questions from CSPI and Verbatim Answers (Conveyed via Amazon message or email, all dates are in 2019)

Q: Are there studies showing that women taking Pink Stork's Fertility supplement or Fertility Sweets candy, or the amount of any of its ingredients, are more likely to become pregnant than women who don't? I notice that two recent meta-analyses of the best studies of myo-inositol concluded that it did not increase a woman's chances of becoming pregnant. Incidentally, the label of the Sweets recommends up to 6 pieces a day. Women who take 4 or more will exceed the Tolerable Upper Intake Levels for folate and zinc, established by the Institute of Medicine's Food and Nutrition Board. (emailed via amazon Jan 30)

A: No response

Q: Are there studies showing that women taking Pink Stork's Fertility supplement or Fertility Sweets candy, or the amount of any of its ingredients, are more likely to become pregnant? Second request. (emailed via amazon Feb 28) A: No response

Q: Your Amazon page says your Fertility supplement will boost a woman's fertility. Are there studies showing that women taking Pink Stork's Fertility supplement are more likely to become pregnant? Third request. (emailed via website May 1)

Fertility Health

https://www.leslabs.com/products/fertility-health

LES Labs, Walnut, California https://www.leslabs.com/

Contents: 6 vitamins, 4 minerals, myo-inositol, and dindolylmethane (a derivative of the compound indole-3-carbinol found in cruciferous vegetables)

Claims made on product labels, Seller's website or Seller's Amazon posting:

"Fertility Health is a natural dietary supplement taken to help support female fertility" (website)

"Myo-Inositol is a vitamin-like compound that can help promote fertility, hormonal balance, and menstrual regulation, especially in women with PCOS" (website)

"Ouatrefolic is a highly bioavailable source of folate and has been studied for its role in promoting conception and to carry a pregnancy to term" (website)

"I bought them but I wouldn't take it every day but it did help me get a period every month I always been in regular but know I'm pregnant can't I still take them in my pregnancy." (Website testimonial)
"Natural fertility aid helps promote reproductive health and aids female fertility" (Amazon)

"Fertility Health is a natural dietary supplement taken to help support female fertility and hormonal balance, and to promote a healthy menstrual cycle. The pregnancy support supplement is specifically formulated to aid conception" (Amazon)

"aids female fertility for women planning on pregnancy" (Amazon)

"Safe for PCOS" (Amazon)

Note: Amazon product page shows 5 photos of pregnant women

Questions from CSPI and Verbatim Answers (Conveyed via Amazon message or email, all dates are in 2019)

Q: Is there evidence that women who take Fertility Health are more likely to become pregnant? I see that two recent meta-analyses of the research on myo-inositol concluded that it does not increase the likelihood of becoming pregnant. And two recent monographs on chasteberry by the Alternative Medicine Review and the American Botanical Council do not support the use of chasteberry to promote fertility. Do you know of good research that shows otherwise? (emailed via amazon Feb 8)

A: No response

Q: Is there evidence that women who take Fertility Health are more likely to become pregnant? (emailed via amazon Feb 28)

A: No response

O: Your Amazon page says that the Fertility Health supplement aids female fertility for women planning on pregnancy. Is there evidence that women who take Fertility Health are more likely to become pregnant? (emailed to support@leslabs.com May 1)

Fertility Support for Her

https://www.premamawellness.com/collections/conceive

Premama, Providence, Rhode Island https://www.premamawellness.com/

Contents: Myo-inositol and folate

Claims made on product labels, Seller's website or Seller's Amazon posting:

"if you're trying to conceive" (website)

"Stage 2. Conceive" (website)

"Prep your body for pregnancy with the Birth Control Cleanse, then switch to Fertility Support for Her to promote conception" (website)

"Fertility Support For Her is an unflavored drink mix that provides natural reproductive support for women trying to conceive" (website)

"The #1 selling over-the-counter fertility-enhancing supplement" (website)

"Proven to optimize your chances of conception with Myo-Inositol." (website)

"By helping your body use insulin effectively, Myo-Inositol helps restore ovarian function, and regulates your menstrual cycle in order to promote conception." (website)

"I was a little skeptical, but got pregnant the second cycle taking this, after 8 months of trying. I was also drinking raspberry leaf tea, so it might have been a combination of the two, but I am very happy with the results." (website testimonial)

"I can tell a huge difference in my cycles already - I also have PCOS! This is the first time I have actually had hope in a looonnnggggg time of being able to conceive naturally!! Plan on making another order soon and I'm also going to get my husband the "HIS" drink !!!!!" (website testimonial)

"Myo-inositol is a naturally occurring member of the B vitamin family that is clinically shown to help improve ovulatory function and egg quality, even in case of women with PCOS (Polycystic Ovary Syndrome)." (Amazon)

"By helping your body use insulin effectively, Myo-Inositol helps restore ovarian function, and regulates your menstrual cycle in order to promote conception." (Amazon)

Questions from CSPI and Verbatim Answers (Conveyed via Amazon message or email, all dates are in 2019)

Q: Are there scientific studies showing that women who take Premama Fertility Support are more likely to become pregnant? (emailed via amazon Jan 27)

A: Great question! There are numerous clinical studies on the active ingredients used Premama's fertility support that show an increase in conception rates. Give this a quick read to start your research: https://www.premamawellness.com/blogs/blog/myo-inositol-impact-fertility-pcos

Q: Unfortunately, the document you referred me to doesn't show that women taking myo-inositol are more likely to become pregnant. The first study cited didn't have a control group, so it's impossible to know whether the myo-inositol was any more effective than a placebo. And in the second study cited, women taking myo-inositol were no more likely to become pregnant than the women taking the placebo. Did you see that? It's on page 350 of the study. Two recent meta-analyses that combined the results of the 9 best studies concluded that women taking myo-inositol did not have an increase in conception rates. Is it possible that, while the Premama formula may help ovarian function in some women, this doesn't increase the chances of becoming pregnant? (emailed via amazon Jan 28)

A: We do not have funding at this juncture to conduct clinical studies on the effectiveness. We rely on clinical research of our active ingredients. I think you'll be hard pressed to find any supplement company that can definitively say that their product increases the chances of becoming pregnant. If you do, I'd be very curious to see.

FertilMax for Women

https://actifproducts.com/product/actif-fertility/

American Health LLC, Las Vegas, Nevada https://actifproducts.com

Contents: 9 vitamins, 4 minerals, arginine, carnitine, bromelain, choline, coenzyme Q10, and 2 botanicals (chasteberry berry extract and green tea leaf extract)

Claims made on product labels, Seller's website or Seller's Amazon posting:

"Maximum Ovulation and Fertility Support" (label)

"the most complete and potent fertility support" (website and Amazon)

"Clinically proven formula to help support ovulation and fertilization" (website and Amazon)

"Voted the most trusted brand in fertility support by doctors and clinicians in 2018" (Amazon)

"Proven in published clinical trials to be highly effective in improving ovulation and fertilization" (Amazon)

Questions from CSPI and Verbatim Answers (Conveyed via Amazon message or email, all dates are in 2019)

Q: Where can I find the published clinical trials mentioned on amazon showing FertilMax is highly effective in improving fertilization? (emailed via amazon Jan 14)

A: No response

Q: Where can I find the published clinical trials mentioned on amazon showing FertilMax for Women is highly effective in improving fertilization? (emailed via amazon Jan 30)

A: No response

Q: Are there studies showing that women taking FertilMax for Women are more likely to become pregnant? (emailed via company website Feb 27)

Fertil Pro

https://yadtech.com/product/fertil-pro-women-vitamins-to-boost-fertility/

YadTech, Montreal, Canada https://yadtech.com/

Contents: 4 vitamins, 4 minerals, and 1 botanical (reishi)

Claims made on product labels, Seller's website or Seller's Amazon posting:

"Our products to boost Fertility" (website)

"Supplements that may help you getting pregnant" (website)

"how simply consuming the right vitamins can help you get pregnant, and how fertility supplements can help" (website) "FERTIL PRO® For Women + Vitamin D3 is a scientifically-designed natural fertility supplement for women that contains a number of powerful and potent vitamins and ingredients that have proven to help increase female fertility" (website)

"The primary focus of the natural vitamins and ingredients is to reduce oxidative stress levels to help naturally increase fertility" (website)

"It also boosts overall reproductive health to help women get pregnant easier and faster" (website)

"The FERTIL PRO® For Women + Vitamin D3 formula is a complete female fertility solution" (website)

"The FERTIL PRO for Women Vitamin D3 formula has been tested according to scientific studies and research to ensure the overall effectiveness and safety of the product" (website)

"women can significantly increase their chances of getting pregnant with FERTIL PRO® For Women + Vitamin D3" (website)

"FERTIL PRO for Women + Vitamin D3 is also Health Canada Approved" (website)

"Vitamin D provides various health benefits, including reducing the risk for different types of cancer, treating depression, building strong bones and also improving fertility (website)

"Vitamin D is a fat-soluble vitamin that the human body needs to help create sex hormones and to also regulate cell growth. This is why Vitamin D is so important for getting pregnant. In fact, women who are Vitamin D deficient often suffer from PMS and PCOS, in addition to infertility." (website)

"[Yale] researchers concluded that maintaining healthy Vitamin D levels would help women with getting pregnant, thus demonstrating the crucial relationship between Vitamin D and fertility" (website)

Questions from CSPI and Verbatim Answers (Conveyed via Amazon message or email, all dates are in 2019)

Q: Can you refer me to studies showing that women taking Fertil Pro increase their chances of conceiving? (emailed via amazon Feb 2)

A: Our products are based on scientific evidence of the ingredients. Please feel free to visit our website www.yadtech.com and see related studies.

Q: Recently, I asked your company through Amazon what studies show that women taking Fertil Pro increase their chances of conceiving. You responded: "Our products are based on scientific evidence of the ingredients. Please feel free to visit our website www.yadtech.com and see related studies."

I've looked at the 5 related studies on the Yadtech website, but I don't think they show that Fertil Pro would increase the chances of pregnancy. Your website cites a 9-year old observational study finding an association between vitamin D levels and the chances of pregnancy in women undergoing IVF. Observational trials can't prove cause-and-effect. Your website also cites a 7-year old review of vitamin D and fertility which, after noting that the research is inconsistent and based largely on animal studies and observational studies, concluded "there is insufficient data available to accurately evaluate the effects of vitamin D in women undergoing IVF."

[A review published less than a year ago by researchers from 5 European countries concluded that "it is still not clear whether vitamin D supplementation improves fertility." https://www.ncbi.nlm.nih.gov/pubmed/30322097]
Your website cites a 9-year old review of micronutrients and pregnancy concluding that while micronutrients "may" affect fertility, conclusive evidence is lacking. It cites a 9-year old observational study of micronutrient supplementation in women undergoing IVF that didn't look at the association with pregnancy success. And it cites a 7-year old small pilot study in England that suggested that women who take micronutrient supplementation during ovulation induction have a higher chance of pregnancy. However, the micronutrient formulation in this study differs greatly from what's in Fertil Pro. Plus, what isn't mentioned is that this pilot study was followed up by a larger intervention trial by the same Fertil Pro continued

researchers that was completed in 2014 but never published, presumably because it found no increased pregnancy rates with micronutrient supplementation.

Do you have any other studies showing that Fertil Pro can "help women get pregnant easier and faster?" (emailed via company website April 9)

A: No response

Q: Your website says that Fertil Pro can help women get pregnant easier and faster. Do you have studies showing this? I've looked at the 5 studies cited on the Yadtech website: (1) a 9-year old observational study of vitamin D which wasn't a clinical trial; (2) a 7-year old review of vitamin D and fertility which concluded that "there is insufficient data available to accurately evaluate the effects of vitamin D in women undergoing IVF;" (3) a 9-year old review of micronutrients and pregnancy that states conclusive evidence is lacking whether micronutrients affect fertility; (4) a 9-year old observational study of micronutrient supplementation in women undergoing IVF that didn't even look at the association with pregnancy success; and (5) a 7-year old small pilot study in England of a 21-ingredient multivitamin and mineral product that is vastly different from Fertil Pro. Do you have any other studies showing that Fertil Pro can "help women get pregnant easier and faster?" (emailed to info@yadtech.com May 1)

A: At the moment the studies which are on our website are the ones we have. Our Vitamins are developed by gynecologists and urologist. Our formulas are all based on scientific evidence. Yadtech has been around since 2010 and our fertility products are recommended by 90% of fertility clinics across Canada.

Q: Has Health Canada approved a fertility claim for Yadtech supplements? (emailed to <a href="maileo-e

Q: Yes, but has Health Canada approved a fertility claim for them? (emailed to info@yadtech.com May 21)

A: At the moment Health Canada did not approve any claim. However we are in the process of modifying Fertil Pro MTL and Health Canada will be approving the claim. May 21)

[Note: *Health Canada* has not approved a fertility claim for any Yadtech product as of September 1, 2019.]

FH Pro for Women

https://www.fairhavenhealth.com/fhpro-women

Fairhaven Health, Bellingham, Washington

Contents: 13 vitamins, 8 minerals, 2 botanicals (grape seed extract, trans-resveratrol), inositol and D-chiro inositol, CoQ10, alpha lipoic acid, choline, N-acetyl-L-cysteine (NAC), melatonin, benfotiamine

Claims made on product labels, Seller's website or Seller's Amazon posting:

"Our premium fertility supplement designed to promote egg quality, improve ovulation, and enhance overall fertility." (website)

"FH PRO for Women is an antioxidant-based, comprehensive fertility supplement designed to support female fertility on multiple fronts by addressing cycle regulation, insulin metabolism, egg health, while also providing full preconception multivitamin support." (website)

"Studies indicate that preconception multivitamin supplementation in and of itself may enhance fertility and increase your chances of conception" (website and Amazon)

"vitamins B, D, iron, magnesium, zinc, and iodine, among others- that first enhance your fertility and then support pregnancy wellness" (website and Amazon)

"Studies indicate that preconception multivitamin supplementation in and of itself may enhance fertility and increase your chances of conception" (website and Amazon)

"FH PRO gives you complete nutritional coverage not only for your best fertility but for the health of your future baby" (website and Amazon)

"Myo-Inositol and D-Chiro Inositol, key ingredients in FH PRO for Women, have been studied extensively and found to play an important role in improving ovulation and overall fertility in women who are having issues related to insulin" (website and Amazon)

"The ingredients in FH PRO will begin to work immediately to support overall reproductive health and fertility" (website and Amazon)

"FH PRO is designed to be taken the entire time you are actively trying-to-conceive. Once pregnancy has been confirmed, discontinue and replace with a prenatal vitamin" (website and Amazon)

"Women with PCOS frequently have insulin resistance, which means the cells in their body are not very sensitive to insulin. When cells are resistant to insulin, higher than normal levels of insulin will circulate in the bloodstream, causing higher than normal levels of testosterone, which in turn can interfere with ovulation and menstruation. By supplementing with the myo and d-chiro inositols found in FH PRO, your insulin sensitivity, hormone balance, and fertility will all likely improve" (website)

"When you undergo IVF, IUI, and other fertility treatments, we know how much you have on the line and how emotional that can make you feel. FH PRO is formulated with scientifically-validated vitamins, minerals, antioxidants, and specialty ingredients to support all forms of ART." (website and Amazon)

"Especially Designed For All TTC Including Those with Insulin Resistance or Pursuing IVF or ART" (website and Amazon)

"A clinical-grade supplement designed to promote egg quality, improve ovarian function, and enhance fertility" (Amazon)

"Specifically designed for women undergoing fertility treatments (also known as Assisted Reproductive Technology – ART" (Amazon)

"PROTECTION AGAINST BIRTH DEFECTS – Contains MethylFolate, the Active Form of Vitamin B9 (Folic Acid), Which Has Been Shown to Prevent Neural Tube Birth Defects, Such as Cleft Palate and Spina Bifida" (Website)

Questions from CSPI and Verbatim Answers (Conveyed via Amazon message or email, all dates are in 2019)

Q: The website says that FH Pro is recommended for all TTC women. Is there evidence that women taking FH Pro are more likely to become pregnant, regardless of their fertility status? (emailed to Fairhaven Health June 17)

A: With the exception of FertilAid for Men and FH PRO for Men we do not have results from clinical trials on our specific formulations. FH PRO for Women is currently being used in a clinical trial in an IVF setting looking at fertilization rates, and some other end points, but we do not have data yet. Like all other US manufacturers of dietary supplements in this fertility space (and in other arenas, I suspect), we are relying on data from research performed on individual ingredients, while at the same time investing in clinical research on several of our products...

FH Pro for Women continued

...Generally speaking, we believe (with support of clinical research and a large percentage of the medical professionals who work in fertility) that there are interventions that help women and men "increase their fertility naturally", which include improved diet, exercise, maintaining healthy weight, and taking specific dietary supplements. These interventions have the benefit of improving sperm health, egg health, ovulation frequency, and uterine lining, to name a few, which increase fertility and "help increase your chances of conceiving" or, said slightly differently, "help increase your chances of becoming pregnant." This is the story we share with our customers, and, again, I believe this to be a defensible case.

Mama

https://vitalconcept.com/speciality/female-supplements/mama

Vital Concept, Bulgaria/Biohealth International, Munchberg, Germany https://vitalconcept.com/

Contents: 2 vitamins, selenium, carnitine, arginine, coenzyme Q10, glutathione, oligofructose and fructose

Claims made on product labels, Seller's website or Seller's Amazon posting:

"For future mothers" (website)

"MAMA is a product for women who want to have children" (website)

"MAMA is suitable for...Women undergoing fertility medical treatments. Women who deal with recurring miscarriages" (website)

"The specially crafted formula of fundamental elements can increase the ability of conception" (website)

"MAMA can improve the chances of conception if taken regularly" (website)

"Primary results can be observed even after the first three months, but to achieve maximum results, take MAMA for at least six months" (website)

"The results that can be accomplished with MAMA depend on the combination with appropriate diet, healthy way of living, appropriate physical activity and overal care for the body. The above-mentioned benefits and effects from MAMA vary with different recepients and other external factors" (website)

Testimonial on website product page: "y'all should try it. i had 2 misscarriage and when i found out about this pills i decide to try it ... and it was the best decision i ever made now I'm finally pregnant with a little girl and my blood test came out with vitamin ladies i recommend y'all to try this"

"Suitable for women who want to get pregnant" (website)

"MAMA – Fertility Aid for Women who Want Children" (Amazon)

"Conception Support" (Amazon)

"Protection against oxidative stress. (website)

"MAMA is a product for women who want to have children" (Amazon)

Questions from CSPI and Verbatim Answers (Conveyed via Amazon message or email, all dates are in 2019)

Q: Can you refer me to studies showing that women taking MAMA increase their chances of conceiving? (emailed via amazon Feb 2)

A: Lots of studies could be found in internet that show the basic ingredients of MAMA (Folic Acid (Vitamin B9), L-Carnitine, L-Arganinee, Coenzyme Q10, Vitamin E, Selenium) have the basic impact on female fertility. I will cite a one that is very descriptive https://www.ctfertility.com/2017/07/27/female-and-male-fertility-supplements/, but you also could search for any of listed ingredients on researchgate.net.There is really lots of information, and it is always good to speak with your physicians to be sure of the super quality of or MAMA product.

Q: There may be really lots of "information" out there, but I'm looking for evidence that these ingredients actually increase the chances of getting pregnant. The web page you referred me to doesn't make any claims about increasing the likelihood of pregnancy and doesn't cite any evidence. Are you aware of good studies that show that women taking the ingredients in MAMA are more likely to become pregnant? (emailed via amazon Feb 3)

A: We are offering natural food supplements and not medical pills. As such, specific medical research is not required. Our products' composition is based on multiple studies on different ingredients, which give insights into how they may improve certain processes in the human body. In the MAMA case, we have complex with proven (by many independent sources) ingredients that can support women's body and add healthy substances to their food regime.

Myo-Folate Fertility Drink Mix

https://www.fairhavenhealth.com/myo-inositol-folate

Fairhaven Health, Bellingham, Washington https://www.fairhavenhealth.com

Contents: Myo-inositol and folate

Claims made on product labels, Seller's website or Seller's Amazon posting:

"Drinkable fertility supplement with myo-inositol and folate." (website and Amazon)

"An unflavored powder that mixes with water or juice and is easy on the stomach." (website and Amazon)

"Myo-Inositol supports hormone balance and cycle regularity by helping with insulin metabolism and Folate helps prevent birth defects like spina bifida " (website)

"Common Infertility Cause #1 – Irregular Cycles and Ovulation" (website and Amazon)

"Common Infertility Cause #2 – Poor Egg Quality" (website and Amazon)

"Myo-Folate was formulated based on the science of using two powerful B Family Vitamins to enhance fertility naturally" (website and Amazon)

"Contains B Vitamins for Fertility in Clinically Studied Doses" (website and Amazon)

"Especially Designed For Women with Insulin Resistance or Over Age 30" (website and Amazon)

"I have PCOS, and this has helped regulate my cycle to some degree. I'm still not regular, but this has helped me move in the right direction. I just wish there was an option for buying the powder in bulk. It feels wasteful throwing away the wrappers for each dose, and I'd love for it to reduce the cost too. My doctor has me taking it twice a day." (website testimonial)

"I suffered recurrent pregnancy loss and many failed cycles of IVF with PGS. I took 3 months off and started on this supplement. I am currently 38 weeks with a healthy baby girl from a natural pregnancy. I do believe it helped improve my egg quality." (website testimonial)

"INCLUDES MYO-INOSITOL TO SUPPORT Hormone Balance, Egg Quality and Ovarian Function" (Amazon)
"DRINKABLE SUPPLEMENT – a Convenient Alternative to Swallowing Capsules that is Gentle on Your Stomach"
(Amazon)

Questions from CSPI and Verbatim Answers (Conveyed via Amazon message or email, all dates are in 2019)

Q: The website says that Myo-Folate uses two powerful B family vitamins to enhance fertility naturally. Most studies of myo-inositol tested it in combination with fertility treatments and most good studies found no effect on pregnancy rates. What is the evidence that Myo-Folate enhances fertility (pregnancy) naturally? (emailed to Fairhaven Health June 17)

A: With the exception of FertilAid for Men and FH PRO for Men we do not have results from clinical trials on our specific formulations...Like all other US manufacturers of dietary supplements in this fertility space (and in other arenas, I suspect), we are relying on data from research performed on individual ingredients, while at the same time investing in clinical research on several of our products....

...Generally speaking, we believe (with support of clinical research and a large percentage of the medical professionals who work in fertility) that there are interventions that help women and men "increase their fertility naturally", which include improved diet, exercise, maintaining healthy weight, and taking specific dietary supplements. These interventions have the benefit of improving sperm health, egg health, ovulation frequency, and uterine lining, to name a few, which increase fertility and "help increase your chances of conceiving" or, said slightly differently, "help increase your chances of becoming pregnant." This is the story we share with our customers, and, again, I believe this to be a defensible case.

doctorMK's Myo-inositol

https://doctormksnatural.com/collections/supplements/products/pcos-support-supplement-myo-inositol

Doctor MK's Natural, Raleigh, North Carolina https://doctormksnatural.com/

Contents: Myo-inositol

Claims made on product labels, Seller's website or Seller's Amazon posting:

"Myo-Inositol for PCOS" (website)

"FERTILITY AND PREGNANCY HELP: Studies show that 2 grams - 4 grams of Myo-Inositol daily improves PCOS symptoms which may help some women to get pregnant by reducing insulin levels (NOTE: This may not work for everyone)" (website)

"Studies show that 2 grams - 4 grams daily have been shown to improve PCOS symptoms" (website)

"PHYSICIAN FORMULATED: At Doctor MK's we know that PCOS can be stressful. Our goal is to help women overcome infertility and increase pregnancy rates without the unwanted side effects of prescription medications" (website and Amazon)

"PCOS SUPPLEMENTS: Myo Inositol is a natural compound that has been shown to lower elevated blood insulin levels, which research is showing to be one of the causes of Polycystic Ovarian Syndrome" (website)

"About this PCOS Supplement. Myo-Inositol, Inositol, has been shown to help with [...] PCOS symptoms" (Amazon) "Myo-Inositol for PCOS and Infertility Issues" (Amazon)

"Myo-Inosito been studied in infertile women with PCOS, with MYO showing the most promise in improving ovulation and egg quality. In a study published in 2007 in Gynecological Endocrinology, 25 women received MYO (4g/day) for six months. The results: 88% of patients had one spontaneous menstrual cycle during treatment, of whom 72% maintained normal ovulatory activity. A total of 10 pregnancies (40% of patients) were obtained." (Amazon)

Questions from CSPI and Verbatim Answers (Conveyed via Amazon message or email, all dates are in 2019)

Website: "All of our orders are managed by Amazon. If you have any concerns about your product or your purchase please contact Amazon"

Q: Two recent systematic reviews and meta-analyses found that women taking myo-inositol were not more likely to become pregnant. What is the evidence that women taking doctorMK's myo-inositol are more likely to become pregnant? (emailed via amazon Jan 27)

A: No response

Q: Is there evidence that women taking doctorMK's myo-inositol are more likely to become pregnant? emailed via amazon Feb 28)

A: Amazon will not allow us to give medical advice, so I cannot violate their terms, but a quick Google search will show the exact answer you are looking for from a variety of sources and perspectives.

Q: In response to my question "Is there evidence that women taking doctorMK's myo-inositol are more likely to become pregnant?," you responded "Amazon will not allow us to give medical advice, so I cannot violate their terms, but a quick Google search will show the exact answer you are looking for from a variety of sources and perspectives." I am not seeking medical advice, just the evidence that doctorMK's myo-inositol affects the likelihood of becoming pregnant, as the website suggests. A Google search does show a variety of claims, but not much hard evidence. The Raffone et al study cited on the doctorMK website was not placebo controlled. An Italian meta-analysis published 6 months ago looking at 8 placebo-controlled studies found that myo-inositol had no effect on pregnancy rates in women undergoing IVF. (emailed via amazon Mar 4)

A: No response

Q: What is the evidence that women taking doctorMK's myo-inositol are more likely to become pregnant? Most studies, although small, don't show that. (emailed to doctormksnatural@gmail.com May 15)

Fairheaven Health Myo-Inositol

https://www.fairhavenhealth.com/myo-inositol

Fairhaven Health, Bellingham, Washington

Contents: Myo-inositol

Claims made on product labels, Seller's website or Seller's Amazon posting:

"formulated to enhance fertility" (label)

"The Natural Choice in Reproductive Health" (label)

"Promotes female AND male fertility." (website)

"Common Infertility Cause #1 – Irregular Cycles and Ovulation" (website and Amazon)

"Common Infertility Cause #2 – Poor Sperm Parameters" (website and Amazon)

"Common Infertility Cause #3 – Poor Egg Quality" (website and Amazon)

"Myo-Inositol has been studied extensively and found to play an important role in improving ovulation and overall fertility in women who are having issues related to insulin" (website and Amazon)

"Supplying extra myo-inositol to women with hormonal imbalance, insulin resistance, or ovarian cysts helps correct the malfunctioning insulin pathways and reduce the signs and symptoms of insulin resistance." (website and Amazon) "Myo-inositol is well-studied antioxidant that mitigates the effects of free radicals on eggs being stored in the ovarian reserve." (website and Amazon)

"Contains B Vitamins for Fertility in Clinically Studied Doses" (website and Amazon)

"Especially Designed For Women with Insulin Resistance" (website and Amazon)

"After 2.5 years of trying to get pregnant with PCOS, I was able to get pregnant after 5 months of taking myoinositol and noticed shorter, more predictable cycles within the first month. Previously I would go months without a period, but had one 35 days after starting this as prescribed." (website testimonial)

"We have been "trying" to conceive since we got married in 2015. A friend told me about this product and I ordered it without hesitation thinking if anything, maybe my cycles would be regular making it easier to conceive. I did not even take this product for a full month and we just got our BIG POSITIVE last night, and again this morning. I am not sure if it is a coincidence but after trying to get pregnant for years, this was the ONLY thing we changed. I highly recommend it to anyone struggling with conceiving & see how it can work for you!" (website testimonial)

Questions from CSPI and Verbatim Answers (Conveyed via Amazon message or email, all dates are in 2019)

Q: What is the evidence that myo-inositol "raises fertility rates," as the website claims? Most good studies find no effect on pregnancy rates. (emailed to Fairhaven Health June 17)

A: With the exception of FertilAid for Men and FH PRO for Men we do not have results from clinical trials on our specific formulations...Like all other US manufacturers of dietary supplements in this fertility space (and in other arenas, I suspect), we are relying on data from research performed on individual ingredients, while at the same time investing in clinical research on several of our products....

...Generally speaking, we believe (with support of clinical research and a large percentage of the medical professionals who work in fertility) that there are interventions that help women and men "increase their fertility naturally", which include improved diet, exercise, maintaining healthy weight, and taking specific dietary supplements. These interventions have the benefit of improving sperm health, egg health, ovulation frequency, and uterine lining, to name a few, which increase fertility and "help increase your chances of conceiving" or, said slightly differently, "help increase your chances of becoming pregnant." This is the story we share with our customers, and, again, I believe this to be a defensible case.

FreshNutrition myo-inositol

https://fresh-nutrition.com/products/myo-inositol-2200mg

Fresh Nutrition, Keizer, Oregon https://fresh-nutrition.com/

Contents: Myo-inositol

Claims made on product labels, Seller's website or Seller's Amazon posting:

"Designed for women with PCOS" (label)

"Bring significant health benefit for women with polycystic ovary syndrome (PCOS)" (label)

Note: On the website, the label bears the PCOS language above. On Amazon, the label is different and does not mention PCOS.

"This is a great product. I am 12 weeks pregnant and it is keeping my blood sugar levels down. I also believe that it has helped me to not have a miscarriage. Myo inositol is an excellent natural way to help women get pregnant stay pregnant and manage diabetes better, highly recommend." (website testimonial)

"STRONGEST AVAILABLE: Our New Myo Inositol is at a strength of 2200mg, meaning it is probably the strongest available on Amazon for PCOS and Hormonal Support." (Amazon)

"SIDE EFFECT FREE PCOS TREATMENT: Shown to lower elevated blood insulin levels, which research has shown to be the cause of PCOS. A completely safe and natural solution for Polycystic Ovarian Syndrome. Our supplement supports healthy ovarian function, hormonal balance, a healthy menstrual cycle, egg quality and overall reproductive health." (Amazon)

"studies have shown that 2-4g daily may help some women to get pregnant (NOTE: Will not work for everyone)" (Amazon)

Questions from CSPI and Verbatim Answers (Conveyed via Amazon message or email, all dates are in 2019)

Q: Your website says that myo-inositol can possibly help some women become pregnant. But the latest scientific reviews and meta-analyses conclude that evidence is lacking that myo-inositol, with or without IVF, increases the likelihood of becoming pregnant. Do you have good evidence that myo-inositol can improve the chances of becoming pregnant? Thanks (emailed to info@fresh-nutrition.com March 21)

A: No response

Q: Are there studies showing that Fresh Nutrition's myo-inositol can improve the chances of becoming pregnant more than a placebo? (emailed to info@fresh-nutrition.com May 15)

A: No response

Q: Are there studies showing that Fresh Nutrition's myo-inositol can improve the chances of becoming pregnant more than a placebo? (emailed to info@fresh-nutrition.com June 10)

Myo and D-Chiro Inositol

https://www.pac-pure.com/product/myo-inositol-d-chiro-inositol-blend/

Pac Pure Nutrition, Salt Lake City, Utah

https://www.pac-pure.com/

Note: Website now redirects to spam page; website claims not double-checked 9/4/2019

Contents: Myo-inositol, D-chiro-inositol

Claims made on product labels, Seller's website or Seller's Amazon posting:

"Lab-Formulated Insulin Support & Fertility Blend" (label)

"Naturally support hormone balance, ovarian function, egg quality, fertility and insulin usage" (website)

"Formulated for women with PCOS" (website)

" 100% NATURAL FERTILITY, HORMONE, AND MENSTRUAL SUPPORT: Hormones affect so many aspects of your life. Our Myo-Inositol and D-Chiro Inositol Blend supports healthy ovarian function, provides hormonal balance, insulin support, weight management, blood pressure health, promotes a healthy menstrual cycle, egg quality, and overall reproductive health." (Amazon)

"INOSITOL, A NATURAL SOLUTION FOR PCOS" (Amazon)

"PROMOTES INSULIN SENSITIVITY & CIRCULATION" (Amazon

Questions from CSPI and Verbatim Answers (Conveyed via Amazon message or email, all dates are in 2019)

Q: Two recent systematic reviews and meta-analyses found that women taking myo-inositol were not more likely to become pregnant. Is there scientific evidence that women taking PacPure inositol are more likely to become pregnant? (emailed via amazon Jan 27)

A: Our Myo-Inositol Blend is intended to help women with hormonal unbalances and also to provide ovarian support. Many studies prove the effectivity of the combination of Myo-Inositol and D-Chiro Inositol in women with polycystic ovary syndrome (PCOS).

Many hormonal and reproductive impairments associated with this disorder seem relieved by the supplement, but we have NOT conducted any specific study regarding the direct impact of Inositol on fertility and pregnancy.

I have received many good reviews from our customers in relation to our Inositol blend. Recent meta-analysis demonstrated how this combination of ingredients is effective in promoting ovulation in patients with PCOS, and in improving the metabolic profile of women with PCOS, concomitantly reducing their hyperandrogenism, which could end up increasing the chances of pregnancy.

However, I always recommend consulting with your doctor before you start taking our Natural Supplements, even more so if you have a known medical condition, or if you are taking prescribed medicines or following any treatments.

Myo-inositol (Vivorigins)

https://vivorigins.com/products/our-myo-inositol-supports-women-who-have-pcos-who-want-to-improve-their-fertility-and-regulate-insulin-sensitivity

VivOrigins (Grapevine, Texas)

https://vivorigins.com/

Contents: Myo-inositol

Claims made on product labels, Seller's website or Seller's Amazon posting:

"Fertility & Reproductive Health" (label)

"Vivorigins MYO-INOSITOL promotes hormonal balance, supports ovarian function and egg quality: specially formulated for women, our Myo-Inositol Capsules support healthy ovarian function, hormonal balance, healthy menstrual cycle, egg quality, and overall reproductive health." (website)

"Myo-inositol helps women suffering from Polycystic Ovary Syndrome (PCOS) who want to improve their fertility" (website)

"Designed For Women Suffering From PCOS: Myo-Inositol has been specially designed for women suffering from Polycystic Ovarian Syndrome (PCOS) who want to improve their fertility and regulate their insulin sensitivity. Myo-Inositol is a natural compound that has been shown to lower elevated blood insulin levels, which research is showing to be one of the causes of PCOS." (website)

Questions from CSPI and Verbatim Answers (Conveyed via Amazon message or email, all dates are in 2019)

Q: Can you refer me to studies showing that Vivorigins myo-inositol helps women with PCOS improve their fertility? I see there are two recent meta-analyses of M-I studies that found that taking myo-inositol did not increase the chances of giving birth. (emailed via amazon Feb 2)

A: No response

Are there studies showing that women taking Vivorigins myo-inositol increase their chances of becoming pregnant? Second request. (emailed via amazon Feb 28)

A: No response

Q: Are there studies showing that women taking Vivorigins myo-inositol increase their chances of becoming pregnant? (emailed to info@vivorigins.com May 15)

A: No response

Q: Are there studies showing that women taking Vivorigins myo-inositol increase their chances of becoming pregnant? (emailed to info@vivorigins.com June 10)

Myo-inositol (Zazzee Naturals)

https://www.amazon.com/dp/Bo1JZNBP92

Zazzee Naturals, Valley Cottage, New York

Note: No Zazzee company website. Dexterity Health, LLC, owns the Zazzee trademark. No address or website.

Contents: Myo-inositol

Claims made on product labels, Seller's website or Seller's Amazon posting:

"FERTILITY, HORMONE, AND MENSTRUAL SUPPORT: Specially formulated for women, our Myo-Inositol Capsules support healthy ovarian function, hormonal balance, a healthy menstrual cycle, egg quality, and overall reproductive health" (Amazon)

"Indications: Fertility, Hormone Balance, Ovarian Function, Reproductive Health, Regular Cycle" (Amazon) "Myo-Inositol supports healthy blood insulin levels, which more and more research is showing supports healthy fertility" (Amazon)

"Myo-Inositol has been shown to support healthy healthy blood insulin levels, which more and more research is showing supports healthy fertility" (Amazon)

"the ideal dosage for fertility and reproductive support" (Amazon)

Questions from CSPI and Verbatim Answers (Conveyed via Amazon message or email, all dates are in 2019)

Q: Is there a study showing that women taking Myo-inositol are more likely to become pregnant? (emailed via amazon Jan 17)

A: "There are lots of studies and literature showing that Myo-Inositol promotes fertility.... If you search online for something like "myo-inositol studies fertility", you will quickly find relevant studies showing support for using Myo-Inositol to treat fertility."

Q: Does "promotes fertility" by myo-inositol mean that it increases the likelihood of becoming pregnant? Because that doesn't seem to be clear in the literature. Two recent meta-analyses of the best studies concluded that myo-inositol does not increase the chances of becoming pregnant. Is it possible that myo-inositol improves ovarian function but not the likelihood of becoming pregnant? (emailed via amazon Jan 30)

A: The way I understand it is that Myo-Inositol does not directly promote fertility, but rather, works to improve hormone balance and ovarian function, which, in turn, make it more like to conceive...If you search for an article titled, "A Combined Therapy with Myo-Inositol and D-Chiro-Inositol Improves Endocrine Parameters and Insulin Resistance in PCOS Young Overweight Women", you will find a study supporting the 40:1 ratio. Also, if you search on PCOS support groups, there is a lot of dialog about taking Myo and D-Chiro in this ratio.

Q: But does Zazzee have evidence that myo-inositol even indirectly makes it more like to conceive? Two recent meta-analyses of the best studies available both concluded that it does not...These two meta-analyses from Spain and Italy found no effect on pregnancy rates: "Inositol supplementation in women with polycystic ovary syndrome undergoing intracytoplasmic sperm injection: a systematic review and meta-analysis of randomized controlled trials." "Myo-inositol supplementation reduces the amount of gonadotropins and length of ovarian stimulation in women undergoing IVF: a systematic review and meta-analysis of randomized controlled trials." To be fair, this recent Chinese meta-analysis did find an effect: "Inositol supplement improves clinical pregnancy rate in infertile women undergoing ovulation induction for ICSI or IVF-ET." This recent Cochrane Collaboration review of the evidence found it "uncertain" whether MI affects pregnancy rate: "Inositol for subfertile women with polycystic ovary syndrome." (emailed via amazon Jan 31)

A: Thanks for sending the titles of the studies. I was able to quickly find all 4 studies that you referenced. I sent your email to the manufacturer, based in the US, who seems to know just about everything about everything, for his comments. I'll be in touch as soon as I heard back from him.

Q: Did you hear back? What did he say? (emailed via amazon Feb 26)

A: I'm sorry for the delay on this. I just received a long, detailed response from the manufacturer, which I'm forward to you, below. I hope this helps:

"Regarding the abstract found at [28756130], their point is that Myo supplementation was insufficient to improve oocyte quality specifically in women with PCOS undergoing intracytoplasmic sperm injection (ICSI). Now, we have to consider what ICSI is. It stands for Intracytoplasmic Sperm Injection and it is an in vitro fertilization procedure in

Zazzee Naturals Myo-Inositol continued

which a single sperm cell is injected directly into the cytoplasm of an egg. Since this type of procedure has a limited success rate anyway, it would make sense that Myo supplementation would not make that much of a difference. In addition, the paragraph concludes that future studies of appropriate dose, size and duration of DCI (D-Chiro Inositol) are vital to clarify its role in the management of PCOS. The article does not specify what doses were used in the randomized controlled trials, the size (I suppose they mean strength) of the product and the duration of the trials, all which play a vital role in the product's success....

Regarding the abstract found at [30078122], the purpose of the study is to "evaluate whether oral myo-inositol supplementation (MI) is able to reduce the amount of gonadotropins (GA) and the length of controlled ovarian hyperstimulation (SL) in both Polycystic Ovarian Syndrome (PCOS) and non-PCOS women undergoing in vitro fertilization (IVF)." The customer indicates that the meta-analyses found that Myo-Inositol does not support fertility. However, the conclusion of this abstract says something contrary: "During IVF, MI is effective in both PCOS and non-PCOS women in saving gonadotropins, but reduces efficiently SL only in PCOS women." My understanding is that if Myo-Inositol was effective in helping PCOS and non-PCOS women in saving gonadotropins, and it helped PCOS women reduce SL (Ovarian Hyperstimulation). The way I read this is that Myo Inositol does help fertility. We also have to take into account the doses used and duration of the study.

[Note: There was no significant difference in pregnancy rates between women given myo-inositol and women in the control groups for the 5 studies and meta-analysis of the 5 studies in the above meta-analysis.]

The 3rd abstract ([29245250]), concludes as follows: "Myoinositol supplement increase clinical pregnancy rate in infertile women undergoing ovulation induction for ICSI or IVF-ET. It may improve the quality of embryos, and reduce the unsuitable oocytes and required amount of stimulation drugs." I suppose the customer can argue that one abstract contradicts the other. However, since neither of these abstracts indicate the exact dose(s) and specific duration of the trials, it is difficult to assess why that might appear to be the case.

[Note: Three of the six studies in the 3^{rd} abstract were open-label or observational studies, not randomized controlled trials.]

Finally, regarding the [Cochrane Collaboration review] article, the circumstances point to a similar scenario as outlined above in the first abstract: The author mentions that he/she is uncertain whether MI improves live birth rate or clinical pregnancy rate in subfertile women with PCOS undergoing IVF pre-treatment taking MI compared to standard treatment. The uncertainty of the author due to the evidence (or lack of it) found does not negate the potential efficacy of the product (again, dose and length of study have to be taken into account)."

Myo-Inositol Plus

https://omnibiotics.com/myo-inositol-d-chiro-inositol/

Omnibiotics, Jackson, Wyoming https://omnibiotics.com/

Contents: Myo-inositol, D-chiro-inositol

Claims made on product labels, Seller's website or Seller's Amazon posting:

"Myo-inositol is believed to improve female fertility by promoting proper utilization of the insulin hormone. What's often seen in women with PCOS and insulin resistance, is the body has trouble converting myo-inositol into D-Chiro-Inositol. This is why including D-Chiro-Inositol in your Inositol supplementation can be so crucial." (website) "The ingredients in Myo-Inositol Plus™ may be effective at mitigating symptoms of various mental health-related conditions associated with insulin resistance and PCOS, including anxiety, binge eating, PMS, PMDD, mood swings, depression, panic attacks and more." (website)

"Natural Fertility Support" (website)

"PCOS Supplement" (Amazon)

"HORMONE, FERTILITY + MENSTRUAL CYCLE SUPPORT" (Amazon)

"MOST EFFECTIVE 40:1 RATIO – Studies show that the body's natural 40:1 ratio of Myo-Inositol to D-Chiro-Inositol is the most effective ratio for fertility and reproductive support. Myo-Inositol Plus offers this clinically-proven 40:1 ratio and features Caronositol, a natural D-chiro-inositol (DCI) botanical extract (minimum 95%), purified from carob pods through a solvent-free patented process." (Amazon)

"Myo-inositol helps support female fertility by promoting proper utilization of the body's natural insulin hormone. Healthy blood insulin levels have been shown to support healthy fertility" (Amazon)

"Indications: Hormone Balance, Ovarian Support, Menopause, Fertility, Menstrual cycle support" (Amazon)

Questions from CSPI and Verbatim Answers (Conveyed via Amazon message or email, all dates are in 2019)

Q: Two recent systematic reviews/meta-analyses found that taking myo-inositol did not increase the likelihood of becoming pregnant for women with PCOS or women undergoing IVF. Is there better evidence available showing that Myo-inositol Plus can improve female fertility? (emailed to info@omnibiotics.com Jan 17)

A: No response

Q: Can you refer me to studies showing that Omnibiotics Myo-Inositol helps improve female fertility? I see there are two recent meta-analyses of M-I studies that found that taking myo-inositol did not increase the chances of giving birth. (emailed to info@omnibiotics.com Feb 2)

A: No response

Q: Can you refer me to studies showing that Omnibiotics Myo-Inositol helps improve female fertility? I see there are two recent meta-analyses of myo-inositol studies that found that taking myo-inositol did not increase the chances of giving birth. (emailed to info@omnibiotics.com June 10)

NeoQ10 Coenzyme Q10 Supplement

https://theralogix.com/products/neoq10-coenzyme-q10-supplement

Theralogix, LLC, Rockville, Maryland https://theralogix.com/

Contents: Coenzyme Q10, vitamin E

Claims made on product labels, Seller's website or Seller's Amazon posting:

"CoO10 supports...female fertility by promoting egg quality"

"COQ10 FOR FERTILITY. CoQ10 supports male fertility by promoting sperm motility, and female fertility by promoting egg quality."

"Supports heart health, healthy blood pressure levels, and maintains optimal CoQ10 levels in people taking statins." (Amazon)

"Supports female fertility by increasing mitochondrial energy production for improved egg quality" (Amazon)

Questions from CSPI and Verbatim Answers (Conveyed via Amazon message or email, all dates are in 2019)

Q: Is there evidence that women taking the CoQ10 in NeoQ10 increase their chances of becoming pregnant? I don't find any studies showing that. Also, I see at clinicaltrials.gov that a small pilot study of NeoQ10 was completed a year ago, but the results are not posted yet. Are these results available? (emailed to support@theralogixhelp.zendesk.com April 9)

A: CoQ10 is involved in mitochondrial energy production. Because of their high energy requirements, oocytes have more mitochondria than any other cell. Cellular production of CoQ10 decreases with age, which is thought to be associated with reduced oocyte energy production, leading to poorer fertilization, chromosomal abnormalities and early pregnancy loss. In one trial, CoQ10 was tested in women (age 35-43) undergoing IVF. As expected in the fertility setting, recruitment for this placebo-controlled trial was quite difficult, and the study was underpowered to show statistically significant results. The study was also stopped early due to another study published showing some damaging effects of polar body biopsy on embryo quality and implantation. The data is promising, however, with a lower rate of aneuploidy in the CoQ10 group. http://www.ncbi.nlm.nih.gov/pubmed/24987272

Here are a couple of other links to papers that may be of interest-

The aging oocyte--can mitochondrial function be improved? https://www.ncbi.nlm.nih.gov/pubmed/23273985 Coenzyme Q10 content in follicular fluid and its relationship with oocyte fertilization and embryo grading https://www.ncbi.nlm.nih.gov/pubmed/22139446

Q: Is there evidence that supplementing with CoQ10 to boost mitochondrial energy production is enough to increase the chances of a woman becoming pregnant? You say the Bentov et al study is promising, but this study is now 5 years old. Are there CoQ10 studies since then showing increased pregnancy rates? Also, the women in the Bentov et al study were undergoing IVF. Is there evidence that CoQ10 is also effective in women not undergoing IVF? Finally, I see at clinicaltrials.gov that a small pilot study of NeoQ10 was completed a year ago, but the results are not posted yet. Are these results available? (emailed to Theralogix @theralogixhelp.zendesk.com via gmail May 6)
A: No response

Q: Is there evidence that supplementing with CoQ10 to boost mitochondrial energy production is enough to increase the chances of a woman becoming pregnant? The Bentov et al study Theralogix referred me to is promising, but this study is now 5 years old. Are there CoQ10 studies since then showing increased pregnancy rates? Also, the women in the Bentov et al study were undergoing IVF. Is there evidence that CoQ10 is also effective in women not undergoing IVF? Also, I see at clinicaltrials.gov that a small pilot study of NeoQ10 was completed a year ago, but the results are not posted yet. Are these results available? (emailed to Theralogix @theralogixhelp.zendesk.com June 10)

A: The studies on CoQ10 are looking more at improving oocyte quality resulting in fewer chromosomal abnormalities and lower risk of miscarriage. I do not know of any CoQ10 studies that looked at the outcome of increasing pregnancy rate. I did a quick review and I could not find any CoQ10 studies in women not undergoing IVF. I just spoke with our VP of Research and Education and the results of the pilot study using NeoQ10 have not been shared with us.

Ovaboost

https://www.fairhavenhealth.com/ovaboost

Fairhaven Health, Bellingham, Washington New York, New York

Contents: Myo-inositol, vitamin E, folate, alpha lipoic acid, Coenzyme Q10, melatonin and 1 botanical (grapeseed extract)

Claims made on product labels, Seller's website or Seller's Amazon posting:

"Doctor-designed fertility supplement to support egg health and ovarian function." (website and Amazon)

"OvaBoost is designed to support female fertility by promoting ovarian function, regular ovulation, and egg health." (website)

"Irregular Ovulation and Insulin Resistance Don't Have to Keep You from Getting Pregnant" (website and Amazon)

"Myo-Inositol, a key ingredient in OvaBoost, has been studied extensively and found to play an important role in improving ovulation and overall fertility in women who are having issues related to insulin" (website and Amazon)

"OvaBoost Fertility Supplement Is Designed to Address Two Common Causes of Female Infertility: cause #1 - Irregular Cycles and Ovulation...

Cause #2 – Poor Egg Quality" (website and Amazon)

"We recommend taking OvaBoost for a minimum of 3 months, or as long as you are actively trying to conceive.

OvaBoost can be discontinued once pregnancy has been confirmed" (website and Amazon)

"By supplementing with myo-inositol, a key ingredient in OvaBoost, insulin sensitivity is improved, hormone balance is restored, and fertility is increased" (website and Amazon)

"Contains B Vitamins for Fertility in Clinically Studied Doses" (website and Amazon)

"I had a history of 2 miscarriages (both at about 5 weeks) the doctors had no explanation of why I had them. I was hurt diagnosed with anything. But now I'm 4 months pregnant and I have to give all the credit to God, this product, and fertile cm." (website testimonial)

"Designed to improve overall female reproductive health and encourage hormonal balance, cycle regularity, and attainment of pregnancy" (website)

"Recommended for all trying-to-conceive women, and particularly women trying to conceive later in life & women with PCOS" (Amazon)

"DOCTOR-DESIGNED, SAFE, & RECOMMENDED FOR ALL TRYING-TO-CONCEIVE WOMEN - Particularly Effective for Women Over 30 & Women with Insulin Resistance" (Amazon)

Questions from CSPI and Verbatim Answers (Conveyed via Amazon message or email, all dates are in 2019)

Q: Is there evidence that the amounts of the ingredients in Ovaboost raise fertility rates, as the website claims? (emailed to Fairhaven Health June 17)

A: I don't see where we say OvaBoost raises fertility rates. Can you point me to that reference?

With the exception of FertilAid for Men and FH PRO for Men we do not have results from clinical trials on our specific formulations. FH PRO for Women is currently being used in a clinical trial in an IVF setting looking at fertilization rates, and some other end points, but we do not have data yet. Like all other US manufacturers of dietary supplements in this fertility space (and in other arenas, I suspect), we are relying on data from research performed on individual ingredients, while at the same time investing in clinical research on several of our products......Generally speaking, we believe (with support of clinical research and a large percentage of the medical professionals who work in fertility) that there are interventions that help women and men "increase their fertility naturally", which include improved diet, exercise, maintaining healthy weight, and taking specific dietary supplements. These interventions have the benefit of improving sperm health, egg health, ovulation frequency, and uterine lining, to name a few, which increase fertility and "help increase your chances of conceiving" or, said slightly differently, "help increase your chances of becoming pregnant." This is the story we share with our customers, and, again, I believe this to be a defensible case.

TheraNatal OvaVite

https://theralogix.com/products/theranatal-ovavite-preconception-vitamin

Theralogix, LLC, Rockville, Maryland https://theralogix.com/

Contents: Coenzyme Q10 and vitamin E

Claims made on product labels, Seller's website or Seller's Amazon posting:

"COQ10 FOR FERTILITY. TheraNatal OvaVite contains highly bioavailable CoQ10, to promote egg quality in women in their mid-30s and beyond." (website)

"TheraNatal OvaVite is a daily preconception prenatal supplement for women in their mid-30s and beyond, or for any women with egg quality concerns.* It is designed specifically to prepare your body for pregnancy, with 1,000 mcg (1 mg) of folate, 2,000 IU of vitamin D3, 100 mg of choline, 220 mcg of iodine, 250 mg of highly bioavailable CoQ10 formulated with patented VESIsorb® technology, and other fertility focused ingredients." (website)

"TheraNatal OvaVite is comprised of the TheraNatal Core tablet PLUS two coenzyme Q10 (CoQ10) softgels. CoQ10 is a nutrient that supports mitochondrial energy production for improved egg quality.* Egg quality declines with age, women in their mid-30s and beyond may want to consider TheraNatal OvaVite." (website)

Questions from CSPI and Verbatim Answers (Conveyed via Amazon message or email, all dates are in 2019)

Q: I see that OvaVite is formulated for women in their mid-30s and beyond trying to conceive. Is there evidence that women taking the CoQ10 in OvaVite increase their chances of becoming pregnant? I don't find any studies showing that. Also, I see at clinicaltrials.gov that a small pilot study of NeoQ10 was completed a year ago, but the results are not posted yet. Are these results available? (emailed to support@theralogixhelp.zendesk.com April 9)

A: CoQ10 is involved in mitochondrial energy production. Because of their high energy requirements, oocytes have more mitochondria than any other cell. Cellular production of CoQ10 decreases with age, which is thought to be associated with reduced oocyte energy production, leading to poorer fertilization, chromosomal abnormalities and early pregnancy loss. In one trial, CoQ10 was tested in women (age 35-43) undergoing IVF. As expected in the fertility setting, recruitment for this placebo-controlled trial was quite difficult, and the study was underpowered to show statistically significant results. The study was also stopped early due to another study published showing some damaging effects of polar body biopsy on embryo quality and implantation. The data is promising, however, with a lower rate of aneuploidy in the CoQ10 group. http://www.ncbi.nlm.nih.gov/pubmed/24987272

Here are a couple of other links to papers that may be of interest-

The aging oocyte--can mitochondrial function be improved? https://www.ncbi.nlm.nih.gov/pubmed/23273985 Coenzyme Q10 content in follicular fluid and its relationship with oocyte fertilization and embryo grading https://www.ncbi.nlm.nih.gov/pubmed/22139446

Q: How do you know that supplementing with CoQ10 to boost mitochondrial energy production is enough to increase the chances of a woman becoming pregnant? You say the Bentov et al study is promising, but this study is now 5 years old. Are there any CoQ10 studies since then showing increased pregnancy rates? Also, the women in the Bentov et al study were undergoing IVF. Is there evidence that CoQ10 is also effective in women not undergoing IVF? Finally, I see at clinicaltrials.gov that a small pilot study of NeoQ10 was completed a year ago, but the results are not posted yet. Are these results available? (emailed to support@theralogixhelp.zendesk.com April 9) through gmail May 6)

A: The studies on CoQ10 are looking more at improving oocyte quality resulting in fewer chromosomal abnormalities and lower risk of miscarriage. I do not know of any CoQ10 studies that looked at the outcome of increasing pregnancy rate. I did a quick review and I could not find any CoQ10 studies in women not undergoing IVF. I just spoke with our VP of Research and Education and the results of the pilot study using NeoQ10 have not been shared with us.

Ovoenergen

https://fertilitysupplementstore.com/product-category/ovoenergen/

Fertility Nutraceuticals LLC, New York, New York https://fertilitynutraceuticals.com/

Contents: Coenzyme Q10

Claims made on product labels, Seller's website or Seller's Amazon posting:

"Boost female fertility" (website)

"Mega-dose, pharmaceutical-grade CoO 10 for healthy eggs" (website)

"Recommended for: Women of any age trying to conceive, with or without fertility treatment" (website)

"Research suggests that supplementation with CoQ10 may...Support fertility in aging ovaries" (website)

"Megadose CoQ10 supplement for female fertility" (product insert)

"a mega-dose nutritional supplement of pharmaceutical-grade coenzyme Q10 (CoQ10), developed in collaboration with leading fertility researchers of CoQ10, specifically to enhance female fertility" (product insert)

"Potential benefits: CoQ10 is believed to enhance female fertility by improving egg quality through robust energy metabolism and protection from oxidative stress" (product insert)

"Endorsed by Fertility Experts at Center for Human Reproduction. OVOENERGEN™ was developed in collaboration with physicians at Center for Human Reproduction, a leading IVF center focused on egg development, antioxidants and women's fertility. CHR endorses and recommends OVOENERGEN™ CoQ10." (website)

"OVOENERGEN™ is a high-quality CoQ10 supplement for women's fertility" (Amazon)

Questions from CSPI and Verbatim Answers (Conveyed via Amazon message or email, all dates are in 2019)

Q: Can you refer me to studies showing that women taking Ovoenergen or CoQ10 are more likely to become pregnant than women who don't take it? I notice a recent trial found that CoQ10 didn't make it more likely. Has Dr Casper published any studies showing Ovoenergen increases fertility? (emailed via amazon Jan 30)
A: No response

Q: Can you refer me to studies showing that women taking Ovoenergen or CoQ10 are more likely to become pregnant than women who don't take it? I notice a recent trial found that CoQ10 didn't make it more likely. Has Dr Casper published any studies showing Ovoenergen increases fertility? (emailed via amazon Feb 28)
A: No response

Q: Can you refer me to studies showing that women taking Ovoenergen or CoQ10 are more likely to become pregnant than women who don't take it? Has Dr Casper published any studies showing Ovoenergen boosts fertility? (emailed via company website Mar 11)

PCOSITOL

https://www.amazon.com/PCOSITOL-Myo-Inositol-D-Chiro-Inositol-Easy-Tear-Reproductive/dp/Bo7BYVN57K

Zazzee Naturals, Valley Cottage, New York. Note: No Zazzee company website. Dexterity Health, LLC, owns the Zazzee trademark. No address or website.

Contents: Myo-inositol, D-Chiro-inositol, folic acid

Claims made on product labels, Seller's website or Seller's Amazon posting:

"Clinical grade fertility support" (label)

"supports female fertility & reproductive health" (label)

"enhanced with 200 mcg of folic acid, which has a long, proven history as an effective supplement for enhanced fertility" (Amazon)

"Designed specifically for fertility and reproductive support" (Amazon)

"the ideal ratio for fertility and reproductive support" (Amazon)

"This combination of Myo-Inositol, D-Chiro-Inositol, and Folic Acid is the all-natural treatment of choice for fertility support." (Amazon)

"Indications: Fertility, Hormone Balance, Ovarian Function, Reproductive Health, Regular Cycle" (Amazon)

Questions from CSPI and Verbatim Answers (Conveyed via Amazon message or email, all dates are in 2019)

Q: Is there a study showing that women taking Myo-inositol are more likely to become pregnant? (emailed via amazon Jan 17)A: "There are lots of studies and literature showing that Myo-Inositol promotes fertility.... If you search online for something like "myo-inositol studies fertility", you will quickly find relevant studies showing support for using Myo-Inositol to treat fertility."

Q: Does "promotes fertility" by myo-inositol mean that it increases the likelihood of becoming pregnant? Because that doesn't seem to be clear in the literature. Two recent meta-analyses of the best studies concluded that myo-inositol does not increase the chances of becoming pregnant. Is it possible that myo-inositol improves ovarian function but not the likelihood of becoming pregnant? (emailed via amazon Jan 30)

A: The way I understand it is that Myo-Inositol does not directly promote fertility, but rather, works to improve hormone balance and ovarian function, which, in turn, make it more like to conceive...If you search for an article titled, "A Combined Therapy with Myo-Inositol and D-Chiro-Inositol Improves Endocrine Parameters and Insulin Resistance in PCOS Young Overweight Women", you will find a study supporting the 40:1 ratio. Also, if you search on PCOS support groups, there is a lot of dialog about taking Myo and D-Chiro in this ratio.

Q: But does Zazzee have evidence that myo-inositol even indirectly makes it more like to conceive? Two recent meta-analyses of the best studies available both concluded that it does not...These two meta-analyses from Spain and Italy found no effect on pregnancy rates: "Inositol supplementation in women with polycystic ovary syndrome undergoing intracytoplasmic sperm injection: a systematic review and meta-analysis of randomized controlled trials." "Myo-inositol supplementation reduces the amount of gonadotropins and length of ovarian stimulation in women undergoing IVF: a systematic review and meta-analysis of randomized controlled trials." To be fair, this recent Chinese meta-analysis did find an effect: "Inositol supplement improves clinical pregnancy rate in infertile women undergoing ovulation induction for ICSI or IVF-ET." This recent Cochrane Collaboration review of the evidence found it "uncertain" whether MI affects pregnancy rate: "Inositol for subfertile women with polycystic ovary syndrome." (emailed via amazon Jan 31)

A: Thanks for sending the titles of the studies. I was able to quickly find all 4 studies that you referenced. I sent your email to the manufacturer, based in the US, who seems to know just about everything about everything, for his comments. I'll be in touch as soon as I heard back from him.

O: Did you hear back? What did he say? (emailed via amazon Feb 26)

A: I'm sorry for the delay on this. I just received a long, detailed response from the manufacturer, which I'm forward to you, below. I hope this helps:

"Regarding the abstract found at [28756130], their point is that Myo supplementation was insufficient to improve oocyte quality specifically in women with PCOS undergoing intracytoplasmic sperm injection (ICSI). Now, we have to consider what ICSI is. It stands for Intracytoplasmic Sperm Injection and it is an in vitro fertilization procedure in which a single sperm cell is injected directly into the cytoplasm of an egg. Since this type of procedure has a limited

PCOSitol continued

success rate anyway, it would make sense that Myo supplementation would not make that much of a difference. In addition, the paragraph concludes that future studies of appropriate dose, size and duration of DCI (D-Chiro Inositol) are vital to clarify its role in the management of PCOS. The article does not specify what doses were used in the randomized controlled trials, the size (I suppose they mean strength) of the product and the duration of the trials, all which play a vital role in the product's success....

Regarding the abstract found at [30078122], the purpose of the study is to "evaluate whether oral myo-inositol supplementation (MI) is able to reduce the amount of gonadotropins (GA) and the length of controlled ovarian hyperstimulation (SL) in both Polycystic Ovarian Syndrome (PCOS) and non-PCOS women undergoing in vitro fertilization (IVF)." The customer indicates that the meta-analyses found that Myo-Inositol does not support fertility. However, the conclusion of this abstract says something contrary: "During IVF, MI is effective in both PCOS and non-PCOS women in saving gonadotropins, but reduces efficiently SL only in PCOS women." My understanding is that if Myo-Inositol was effective in helping PCOS and non-PCOS women in saving gonadotropins, and it helped PCOS women reduce SL (Ovarian Hyperstimulation). The way I read this is that Myo Inositol does help fertility. We also have to take into account the doses used and duration of the study.

[Note: There was no significant difference in pregnancy rates between women given myo-inositol and women in the control groups for the 5 studies and meta-analysis of the 5 studies in the above meta-analysis.]

The 3rd abstract ([29245250]), concludes as follows: "Myoinositol supplement increase clinical pregnancy rate in infertile women undergoing ovulation induction for ICSI or IVF-ET. It may improve the quality of embryos, and reduce the unsuitable oocytes and required amount of stimulation drugs." I suppose the customer can argue that one abstract contradicts the other. However, since neither of these abstracts indicate the exact dose(s) and specific duration of the trials, it is difficult to assess why that might appear to be the case.

[Note: Three of the six studies in the 3^{rd} abstract were open-label or observational studies, not randomized controlled trials.]

Finally, regarding the [Cochrane Collaboration review] article, the circumstances point to a similar scenario as outlined above in the first abstract: The author mentions that he/she is uncertain whether MI improves live birth rate or clinical pregnancy rate in subfertile women with PCOS undergoing IVF pre-treatment taking MI compared to standard treatment. The uncertainty of the author due to the evidence (or lack of it) found does not negate the potential efficacy of the product (again, dose and length of study have to be taken into account)."

Pregnancy Prep

https://vitanica.com/all-vitanica-supplements/pregnancy-prep-reproductive-system-support/

Vitanica, Tualatin, Oregon https://vitanica.com/

Contents: 8 botanicals (Tribulis terrestris, chaste tree berry extract, rhodiola rosea extract, maca root extract, dong quai root extract, motherwort aerial parts extract, red raspberry leaf powder, and alfalfa aerial parts extract), amylase, protease, lipase, cellulase, and lactase

Claims made on product labels, Seller's website or Seller's Amazon posting:

"In preparation for pregnancy women can optimize their fertility by supporting regular ovulation and the overall health and tone of the uterus with time-honored and scientifically researched botanicals" (website and Amazon)

"Regular ovulation is promoted with Chaste tree berry and Tribulus. Tribulus has research supporting this function and shows better results for women who took it with the ovulation-stimulating hormonal drug" (website and Amazon)
"Rhodiola is included for general endocrine system support and because research does indicate its support in fertility" (website and Amazon)

"Enzymes are included to promote better nutrient uptake" (website and Amazon)

"Discontinue at first determination of pregnancy" (website)

Questions from CSPI and Verbatim Answers (Conveyed via Amazon message or email, all dates are in 2019)

Q: Are there studies showing that women who take the amounts of the ingredients in Pregnancy Prep are more likely to become pregnant than women who don't? How do we know that its effects on ovulation and the uterus are enough to increase the chances of becoming pregnant? (emailed to www.vitanica.com Jan 30)

A: there is one published study on rhodiola and increased pregnancy in women with history of amenorrhea...

[Note: This was an uncontrolled Russian study involving 200 mg of Rhodiola given orally or by injection to 40 women. 11 became pregnant. The results were presented at a 1970 conference in Russia, but apparently never published in a peer-reviewed journal; the daily dosage of Pregnancy Prep is 100mg or 200mg orally daily];

...There is one published study with maca lowering FSH in perimenopausal women; there are several studies showing that vitex lowers prolactin/ regulates menses by improving ovulation; one unpublished study on tribulus enhancing ovulation rates; the dong quai, motherwort, red raspberry, alfalfa are based on traditional empirical uses of these herbs over generations. Vitanica is coming out with a fertility line of products that will more specifically target select mechanisms involved in infertility-- ex/ one formula for egg quality; another formula for enhancing ovulation; etc. sincerely, tori hudson, n.d.

Pregnitude

https://www.pregnitude.com/

Manufactured by Exeltis USA, Florham Park, New Jersey http://womenshealth.exeltisusa.com/

Contents: Myo-inositol and folic acid

Claims made on product labels, Seller's website or Seller's Amazon posting:

"Trying to get pregnant? The idea of becoming a mother is very exciting, but sometimes it can take longer than you would like. Pregnitude is recommended by doctors for patients who are having difficulty conceiving or are experiencing menstrual irregularities" (label)

"Trying to get Pregnant? Now there's a doctor recommended dietary supplement to support reproductive function formulated for women who may be having difficulty conceiving" (website)

"Pregnitude is recognized as a viable non-prescription option for women who may be having difficulty conceiving" (website)

"Clinically proven* *Based on randomized, double-blind placebo-controlled trial: effects of myo-inositol on ovarian function and metabolic factors in women with PCOS", S.Gerli et al: European Review for Medical and Pharmacological Sciences, 2007 Sep-Oct;11(5):347-54" (website) Note: pregnancy rates were not recorded in this study.

"Option For Women Who May Be Having Difficulty Conceiving" (Amazon)

Questions from CSPI and Verbatim Answers (Conveyed via Amazon message or email, all dates are in 2019)

Q: Is there a study showing that women who take Pregnitude are more likely to become pregnant? Your website says Pregnitude is clinically proven, but the study it cites did not look at pregnancy rates. (emailed via company website Jan 16)

A: No response

Q: Can you refer me to studies showing that Pregnitude can help women become pregnant who may be having difficulty conceiving? None of the four studies described in the Clinical Backgrounder on the Pregnitude website showed an increased rate of pregnancy. Also, I see there are two recent meta-analyses of myo-inositol studies that found that taking myo-inositol did not increase the chances of giving birth. I emailed the company several weeks ago, but got no response. (emailed via amazon Feb 2)

A: Sadly, I don't know the answer to your question. We are not the product manufacturer. As the seller, we only have access to the information available on the product listing page. I'm confident that the manufacturer would be better able to answer your question!

Q: Is there a study showing that women who take Pregnitude are more likely to become pregnant? Your website says Pregnitude is clinically proven, but the study it cites did not look at pregnancy rates. (emailed via company website Feb 3)

A: No response

Q: Is there a study showing that women who take Pregnitude are more likely to become pregnant? Your website says Pregnitude is clinically proven, but the study it cites did not look at pregnancy rates. Second request. (emailed via company website Feb 28)

Pregnositol

https://www.amazon.com/Zazzee-PREGNOSITOL-Powder-Servings-Ideal/dp/Bo7NLDK791

Zazzee Naturals, Valley Cottage, New York. Note: No Zazzee company website. Dexterity Health, LLC, owns the Zazzee trademark. No address or website.

Contents: Myo-inositol, D-Chiro-inositol, and folic acid

Claims made on product labels, Seller's website or Seller's Amazon posting:

"Premium grade fertility support" (label)

"supports female fertility" (label)

"Designed specifically to provide fertility and reproductive support" (Amazon)

"enhanced with 200 mcg of folic acid, which has a long, proven history as an effective supplement for enhanced fertility" (Amazon)

"the ideal ratio for optimal fertility support" (Amazon)

"all-natural support for many fertility issues" (Amazon)

"Indications: Fertility, Hormone Balance, Ovarian Function, Reproductive Health." (Amazon)

Questions from CSPI and Verbatim Answers (Conveyed via Amazon message or email, all dates are in 2019)

Q: Is there a study showing that women taking Myo-inositol are more likely to become pregnant? (emailed via amazon Jan 17)

A: "There are lots of studies and literature showing that Myo-Inositol promotes fertility.... If you search online for something like "myo-inositol studies fertility", you will quickly find relevant studies showing support for using Myo-Inositol to treat fertility."

Q: Does "promotes fertility" by myo-inositol mean that it increases the likelihood of becoming pregnant? Because that doesn't seem to be clear in the literature. Two recent meta-analyses of the best studies concluded that myo-inositol does not increase the chances of becoming pregnant. Is it possible that myo-inositol improves ovarian function but not the likelihood of becoming pregnant? (emailed via amazon Jan 30)

A: The way I understand it is that Myo-Inositol does not directly promote fertility, but rather, works to improve hormone balance and ovarian function, which, in turn, make it more like to conceive...If you search for an article titled, "A Combined Therapy with Myo-Inositol and D-Chiro-Inositol Improves Endocrine Parameters and Insulin Resistance in PCOS Young Overweight Women", you will find a study supporting the 40:1 ratio. Also, if you search on PCOS support groups, there is a lot of dialog about taking Myo and D-Chiro in this ratio.

Q: But does Zazzee have evidence that myo-inositol even indirectly makes it more like to conceive? Two recent meta-analyses of the best studies available both concluded that it does not...These two meta-analyses from Spain and Italy found no effect on pregnancy rates: "Inositol supplementation in women with polycystic ovary syndrome undergoing intracytoplasmic sperm injection: a systematic review and meta-analysis of randomized controlled trials." "Myo-inositol supplementation reduces the amount of gonadotropins and length of ovarian stimulation in women undergoing IVF: a systematic review and meta-analysis of randomized controlled trials." To be fair, this recent Chinese meta-analysis did find an effect: "Inositol supplement improves clinical pregnancy rate in infertile women undergoing ovulation induction for ICSI or IVF-ET." This recent Cochrane Collaboration review of the evidence found it "uncertain" whether MI affects pregnancy rate: "Inositol for subfertile women with polycystic ovary syndrome." (emailed via amazon Jan 31)

A: Thanks for sending the titles of the studies. I was able to quickly find all 4 studies that you referenced. I sent your email to the manufacturer, based in the US, who seems to know just about everything about everything, for his comments. I'll be in touch as soon as I heard back from him.

O: Did you hear back? What did he say? (emailed via amazon Feb 26)

A: I'm sorry for the delay on this. I just received a long, detailed response from the manufacturer, which I'm forward to you, below. I hope this helps:

"Regarding the abstract found at [28756130], their point is that Myo supplementation was insufficient to improve oocyte quality specifically in women with PCOS undergoing intracytoplasmic sperm injection (ICSI). Now, we have to consider what ICSI is. It stands for Intracytoplasmic Sperm Injection and it is an in vitro fertilization procedure in Pregnositol continued

which a single sperm cell is injected directly into the cytoplasm of an egg. Since this type of procedure has a limited success rate anyway, it would make sense that Myo supplementation would not make that much of a difference. In addition, the paragraph concludes that future studies of appropriate dose, size and duration of DCI (D-Chiro Inositol) are vital to clarify its role in the management of PCOS. The article does not specify what doses were used in the randomized controlled trials, the size (I suppose they mean strength) of the product and the duration of the trials, all which play a vital role in the product's success....

Regarding the abstract found at [30078122], the purpose of the study is to "evaluate whether oral myo-inositol supplementation (MI) is able to reduce the amount of gonadotropins (GA) and the length of controlled ovarian hyperstimulation (SL) in both Polycystic Ovarian Syndrome (PCOS) and non-PCOS women undergoing in vitro fertilization (IVF)." The customer indicates that the meta-analyses found that Myo-Inositol does not support fertility. However, the conclusion of this abstract says something contrary: "During IVF, MI is effective in both PCOS and non-PCOS women in saving gonadotropins, but reduces efficiently SL only in PCOS women." My understanding is that if Myo-Inositol was effective in helping PCOS and non-PCOS women in saving gonadotropins, and it helped PCOS women reduce SL (Ovarian Hyperstimulation). The way I read this is that Myo Inositol does help fertility. We also have to take into account the doses used and duration of the study.

[Note: There was no significant difference in pregnancy rates between women given myo-inositol and women in the control groups for the 5 studies and meta-analysis of the 5 studies in the above meta-analysis.]

The 3rd abstract ([29245250]), concludes as follows: "Myoinositol supplement increase clinical pregnancy rate in infertile women undergoing ovulation induction for ICSI or IVF-ET. It may improve the quality of embryos, and reduce the unsuitable oocytes and required amount of stimulation drugs." I suppose the customer can argue that one abstract contradicts the other. However, since neither of these abstracts indicate the exact dose(s) and specific duration of the trials, it is difficult to assess why that might appear to be the case.

[Note: Three of the six studies in the 3^{rd} abstract were open-label or observational studies, not randomized controlled trials.]

Finally, regarding the [Cochrane Collaboration review] article, the circumstances point to a similar scenario as outlined above in the first abstract: The author mentions that he/she is uncertain whether MI improves live birth rate or clinical pregnancy rate in subfertile women with PCOS undergoing IVF pre-treatment taking MI compared to standard treatment. The uncertainty of the author due to the evidence (or lack of it) found does not negate the potential efficacy of the product (again, dose and length of study have to be taken into account)."

ProXeed Women

http://www.proxeed.eu/proxeed-women/

Alfasigma HealthScience BV (Utrecht, The Netherlands) http://www.proxeed.eu/

Contents: 8 vitamins, 4 minerals, carnitine, arginine, and N-acetyl-cysteine

Claims made on product labels, Seller's website or Seller's Amazon posting:

"Supports female fertility and reproduction" (label)

"a patented fertility supplement designed for women who want to enhance their fertility and reproductive health" (website)

"ProXeed Women is recommended for all women who want to optimise their fertility and help increase their chances of pregnancy" (website)

Proxeed Women is recommended for women of reproductive age who: are experiencing fertility problems [...] are preparing for IVF and want to ensure the best possible quality of egg (ovum) and an optimum environment for implantation" (website)

"You should take Proxeed Women for 4-6 months or for as long as you are trying to conceive" (website)

"Proxeed Women works by: encouraging fertilisation, healthy cell division and the implantation of the fertilised egg" (website)

Questions from CSPI and Verbatim Answers (Conveyed via Amazon message or email, all dates are in 2019)

Q: An advertisment for Proxeed says it's "the trusted fertility supplements for couples trying to conceive." Is there a study showing that women who take Proxeed are more likely to conceive? (emailed to amazon seller Subha Enterprise Jan 16)

A: Can you please describe your issue in detail so it will be easy for us to help out. (Jan 16)

Q: You asked: Can you please describe your issue in detail so it will be easy for us to help out. Just this: An advertisment for Proxeed says it's "the trusted fertility supplements for couples trying to conceive." Is there a study showing that women who take Proxeed are more likely to conceive? That's all. (emailed to amazon seller Subha Enterprise Jan 17) A: There are so many studies/information available online proving the facts that proxeed have given positive result of conceiving to woman. (Jan 18)

Q: Thank you for your response to my earlier question asking if there is a study showing that women who take Proxeed are more likely to conceive. You said there are many studies/information available online proving it. Can you refer me to a good study showing that women who take Proxeed or its ingredients increase their likelihood of becoming pregnant? (emailed to amazon seller Subha Enterprise Feb 2)

A: As mentioned in the earlier email there are many information/literature available online. We cannot recommend you any specific articles. We hope you will understand it. (Feb 3)

Q: Do you have studies showing that women who take ProXeed Women increase their chances of pregnancy? (emailed to alfasigma.com May 9 and May 15)

A: Email bounced (May 9 and May 15)

Q: Do you have studies showing that women who take ProXeed Women increase their chances of pregnancy? (emailed via http://www.proxeed.eu/contact-us/ May 10 and May 15)

A: Website wouldn't submit message. Error message: "There is a validation error. Check the required fields and send the message again." But all required fields were filled in. (May 10)

Q: Do you have studies showing that women who take ProXeed Women increase their chances of pregnancy? (emailed through website at http://www.proxeed.eu/contact-us/ June 10)

A: Error message: There is a validation error. Check the required fields and send the message again.

Ready.Set.Go!

https://www.bestnestwellness.com/products/ready-set-go-fertility

Best Nest Wellness, Denver, Colorado https://www.bestnestwellness.com/

Contents: 8 vitaContents: 11 vitamins, 6 minerals, choline, and 5 botanicals (red clover blossom extract, chaste berry extract, ginkgo biloba leaf, ashwagandha powder, shatavari root powder)mins, 4 minerals, carnitine, arginine, and N-acetyl-cysteine

Claims made on product labels, Seller's website or Seller's Amazon posting:

"Developed by a physician, Ready. Set. Go!™ Fertility for Women provides three-in-one support as a complete multi, a fertility blend, and an overall wellness enhancer" (website)

"Packed with 25+ vitamins (including methylcobalamin & methylfolate) and herbs used to assist with conception for centuries" (website)

"I want to have a baby but it hasn't happened yet. I want to make sure that I'm doing everything I can to increase my chances" (statement on website product page)

"Didn't even finish the first full

Bottle and got our BFP after years of trying. What are you waiting for?" (website testimonial)

"Taking charge of your fertility is easy with our supplement" (Amazon product page)

"No need to fuss with making a tea or having to pay thousands for drugs and other treatment methods that can cause side effects." (Amazon)

"When combined with a healthy diet, lifestyle, and fertility monitor, our supplement can improve your chances of conceiving" (Amazon product page)

Questions from CSPI and Verbatim Answers (Conveyed via Amazon message or email, all dates are in 2019)

Q: Your amazon site says the ingredients in Ready.Set.Go! are proven to enhance fertility. Could you refer me to the studies that prove that women who take Ready.Set.Go!, or the amounts of its ingredients, are more likely to become pregnant than women who don't? (emailed via amazon Jan 30)

A: No response

Q: Are there studies showing that women who take Ready.Set.Go!, or the amounts of its ingredients, are more likely to become pregnant? Where can I find them? Second request. (emailed via amazon Feb 28)

A: No response

Q: Are there studies showing that women who take Ready.Set.Go! are more likely to become pregnant? Where can I find them? (emailed via company website Mar 11)

A: No response

- Q: Are there studies showing that women who take Ready.Set.Go! are more likely to become pregnant? Where can I find them? (emailed to support@bestnestwellness.com June 10)
- A: Developed by an expert physician using the latest female fertility research. Ready. Set. Go!™ provides 3-in-1 support for conception:
- 1. It is an antioxidant blend. It contains vitamins, minerals, and herbs that fight the effects of free radicals. Free radicals can affect fertility. Our supplement supports overall health.
- 2. It has a proprietary herbal blend. Our natural formula provides you with the benefits of herbs used for centuries to assist with conception. The herbs help enhance reproductive health to increase your chances of getting pregnant.
- 3. It is a complete prenatal multivitamin that includes methylfolate (natural folic acid), methylcobalamin (natural B12), and pyridoxal-5-phosphate (natural B6). You can be confident your body will absorb the critical nutrients needed for conception. Get a head start on proper nutrition with our supplement.
- Q: But is there any evidence that this 3-in-1 support for conception actually increases the chances of becoming pregnant? (emailed to support@bestnestwellness.com June 13)

A: No response

Women's Fertility Boost

http://concepta.solutions/products/female-fertility/

Concepta Solutions, North Miami Beach, Florida http://concepta.solutions/

Contents: 3 vitamins, zinc, myo-inositol, 5-hydroxytryptophan (5 HTP), melatonin, and 7 botanicals (maca root extract, chaste tree berry, ginkgo biloba extract, tribulis terrestris fruit extract, epimedium aerial parts, shatavari root, dong quai root extract)

Claims made on product labels, Seller's website or Seller's Amazon posting:

"Concepta's Fertility Boost helps to enhance female fertility" (label)

"FEMALE FERTILITY BOOSTER. Our Carefully crafted proprietary blend of vitamins and organic supplements was formulated to promote hormonal balance, enhance sexual health, and stimulate fertility. Individual results may vary depending on a number of factors" (website)

"Vitex is a wondrous herb for fertility helping control a range of issues such as PMS, acne, low progesterone and estrogen, lack of ovulation, and irregular or failed menstrual cycles." (website)

"Studies have shown chaste tree berries can increase the luteal phase by several days, thereby multiplying the chances of successful conception" (website)

"Epimedium in Traditional Chinese Medicine (Yin Yang Huo) has long been taken as a fertility supplement" (website) "Angelica Dong Quai (Angelica sinensis) is reputed to be one of the most powerful female fertility tonic herbs" (website) "In women with PCOS, modest doses of inositol have been seen to reliably and significantly increase ovulation and fertility rates. The pro-fertility and hormone balancing effects of myo-inositol appear to be either additive or synergistic with supplemental melatonin (a plant-sourced peptide hormone) and are further beneficial when paired with Vitamin Bo folic acid" (website)

"While a zinc deficiency won't make you infertile, it can affect the body's normal functioning, which could make it harder for you to get pregnant" (website)

"Riboflavin and Niacin: Known as Vitamins B2 & B3, these vitamins occur naturally in plants and animals. They have been shown to reverse the risk of ovulatory infertility" (website)

"Women's Fertility Booster" (Amazon)

"the ingredients in our herbal blend have been used for centuries in TCM and Ayurvedic Medicine to overcome fertility issues" (Amazon)

"Get the biggest bang for your buck and start your fertility journey with a boost, with our bountiful 45-day supply!" (Amazon)

"For best results, continue using Concepta until conception is achieved" (Amazon)

"We're so confident that Concepta's Fertility Booster will meet your satisfaction, we're taking all the risk with our Satisfaction Guarantee! Try our trusted formula for 90 days - If you're not satisfied, just let us know & you will receive a full refund, no questions asked, no hassles! What do you have to lose?" (Amazon)

"Top benefits of Concepta Women's Fertility Boost...Increased odds of natural & IVF conception" (Amazon)

Questions from CSPI and Verbatim Answers (Conveyed via Amazon message or email, all dates are in 2019)

Q: I assume "reproductive success" means pregnancy. Is there a scientific study showing that Women's Fertility Booster can increase the chances of becoming pregnant? I didn't see any listed on your website. (emailed via amazon Jan 14) A: No response

Q: Is there a scientific study showing that Women's Fertility Boost can increase the chances of becoming pregnant? I didn't see any listed on your website. (emailed via amazon Jan 30)

A: All the ingredients in this product have been shown to correlate with improved ovulation, strengthens egg quality and optimizes reproductive health. I have attached our product guide for this product to this email, so you can take a closer look at some of the benefits.

As well, here are a number of clinical studies related to some of the health benefits of some of the ingredients found in our Women's Fertility supplement.

Women's Fertility Boost continued

M. Walker: Effects of Peruvian Maca on hormonal functions. New World Botanicals Townsend Letter, 1998. [Note: this article offers no evidence that maca affects human pregnancy]

- A. Romm: Botanical Medicine for Women's Health. St. Louis Missouri, Churchill Livingstone, 2010.
- R. Trickey: Women, Hormones and The Menstrual Cycle herbal and medical solutions from adolescence to menopause. Allen & Unwin, 2003.
- D.R. Yance: Adaptogens in Medical Herbalism Elite Herbs and Natural Compounds for Mastering Stress, Aging and Chronic Disease. Healing Arts Press, 2013.
- Q: Your page on amazon says that Women's Fertility Boost increases the odds of conceiving through IVF. Is there a study showing that? (emailed via company website Mar 12)
- A: No response
- Q: I recently asked if there's a scientific study showing that Women's Fertility Booster can increase the chances of becoming pregnant. You attached a product guide, but this didn't come through the Amazon email. So I looked at the document on the Concepta website that describes the ingredients and what they're supposed to do. I found three claims about higher pregnancy rates with Vitex, Myo-inositol/melatonin, and riboflavin/niacin. However, I could find only one study of Vitex and fertility in which it wasn't part of a combination of herbs and Vitex didn't increase the rate of pregnancy. As for myo-inositol, two recent meta-analyses and one systematic review concluded that evidence is lacking that taking myo-inositol increases the chances of pregnancy. I found two studies testing the addition of melatonin to myo-inositol. Neither showed that melatonin increased the pregnancy rate. I couldn't find any study that vitamin B-2 increased human fertility and only one animal study that found that B-3 helped the survival of eggs in mice. You listed what you called clinical studies, but these were monographs and textbooks, not clinical studies. Can you refer me to studies that show that Women's Fertility Booster or its ingredients increases the likelihood of a woman becoming pregnant? (emailed via website March 21)