Evidence of improved absorbability for a dietary supplement cannot, on its own, support claims of improved effectiveness

Basis of Inquiry: As part of NAD’s initiative with the Council for Responsible Nutrition (“CRN”) designed to expand NAD review of advertising claims for dietary supplements, CRN challenged certain advertising claims disseminated by the Quten Research Institute (“Quten”) for its Qunol dietary supplement. The advertising, print and on the Internet, included the following claims:

“300% more absorbable and effective.” “Bioavailability studies, which test the absorbability of a substance in the bloodstream and several dissolution and cell-culture studies have shown Qunol CoQ10 to be 300% more absorbable and 300% more effective than other CoQ10 oral supplements on the market today.”

“Up to 6X better absorption than regular CoQ10.”

“100 mg Qunol Liquid CoQ10 = up to 600 mg regular CoQ10.”

“Clinically Proven”

“Taking Qunol reduces both systolic & diastolic pressure by 10% over an 8 week period.”

“This reduces the risk of heart disease, stroke, kidney disease and dementia.”

“Qunol reduces the fasting blood glucose levels by 33%.” “This shows that Qunol is able to reduce insulin resistance problems by improving the uptake of blood glucose into the cells by 33%.” “Qunol may be beneficial in preventing Type 2 diabetes.”

“Medically Proven Efficacy” [heading] “improve hypertension – essential hypertension and isolated systolic hypertension” [sub-heading]

“Qunol Ultra Co Q10 up to 300 times more effective” [heading] “CoQ10 health benefits” [subheading] ; “antioxidant protection” [“It is estimated that free radicals are responsible for up to 80% of our degenerative diseases – Cancer, Cataract & Early Aging.”], “heart health”, “blood pressure”, “immune health”, [“Studies conducted on HIV/AIDS patients

1 CRN files challenges with the NAD regarding advertising of dietary supplements, in an effort to encourage manufacturers to provide substantiaion for their advertising claims to an objective, third-party for review and evaluation and to assure that claims being promoted to consumers are truthful, not misleading and are substantiated with credible scientific evidence. Through the use of the NAD’s voluntary advertising review program, CRN attempts to identify advertising that may exceed the scientific support for those products and to engage those advertisers to provide their support for those claims or to withdraw those claims or modify them in such a manner that they do reflect the available evidence for substantiation. If the NAD determines that the claims are all truthful, not misleading and well-substantiated, then so much the better – they have helped demonstrate to the industry’s critics that these claims are credible and can be relied upon by consumers.
indicated improvement in immune health with CoQ10 supplementation”), “blood sugar”, “extends youth” (“Taken regularly CoQ10 fights the aging process as it contributes to greater health and longevity”), “periodontal disease” (“Another amazing contribution of CoQ10 is in preventing or correcting gingivitis, inflamed and swollen gums”), “cancer” (“Observational studies of women diagnosed with Breast Cancer have reported reduced blood CoQ10 level, while studies indicate remission or partial remission in patients with tumors who take CoQ10”; “CoQ10 should definitely be used by cancer patients after taking any chemotherapy drug associated with heart toxicity.”), “loss of brain function” (“it might play an important role in preventing degenerative brain diseases such as Alzheimer’s, Parkinson’s & ALS.”); “It may also prevent gradual loss of memory and reduced brain function that is often considered “normal” to aging”), “weight loss” (“CoQ10 is shown to speed up metabolism and contribute to weight loss”,”100mg/day of CoQ10 was shown to produce significant weight loss.”). and “migraine headache” (“CoQ10 reduces both the frequency and the duration of migraine attacks.”) The implied claims of this page of the Qunol CoQ10 website are of particular concern. Available at: http://www.qunol.com/CoQ10HealthBenefits.aspx

“Qunol- Master Antioxidant” [heading]; “Free radicals can cause irreparable cell damage – linked to a range of disorders such as Cancer, Arthritis, Atherosclerosis, Alzheimer’s disease and Diabetes.”

“CoQ10 deficiency has shown to be present in some patients with high blood pressure.”

“CoQ10 is not a specific high blood pressure supplement. Rather, it seems to correct some metabolic abnormality that in turn has a favorable influence on the blood pressure.”

“Doctor recommended CoQ10 formula”

**Challenger’s Position:** CRN challenged claims for “Qunol CoQ10,” which appeared in Costco Connection, a mailer sent to Costco members. CRN noted that the Qunol website, http://www.qunol.com/, also includes many of the same claims, as well as additional ones. Further, CRN stated, these same advertising claims for Qunol CoQ10 also appear on the websites of other major retailers, including Walmart.

CRN had three areas of concern related to the net impression created by the challenged Qunol CoQ10 advertising claims.

**Ingredient benefits vs. product benefits.** CRN stated that certain benefits that are attributed to CoQ10 are being made for the product Qunol CoQ10, despite the advertiser’s significant efforts to differentiate Qunol CoQ10 from regular CoQ10. CRN stated that it is aware of research with respect to the benefits of CoQ10 generally, but added that the research cannot support the specific claims for Qunol CoQ10 claims.

**Comparative claim to regular CoQ10.** CRN stated that it is not aware of any published research that would substantiate the claim that Qunol CoQ10 is 300 times more effective than regular
CoQ10. Discussing the dissolution and cell culture studies cited in support by the advertiser, CRN stated that those studies may substantiate comparative absorption claims, but cannot substantiate any claims regarding effectiveness.

Substantiation for direct and implied disease claims. As stated, the Qunol CoQ10 website makes many direct and implied disease claims. CRN was particularly concerned regarding express and implied claims related to serious diseases (e.g., breast cancer, Alzheimer’s, Parkinson’s, ALS, HIV/AIDS) contending that an advertiser must possess competent and reliable scientific evidence as support. CRN contended that the net impression created by the Qunol CoQ10 website and advertisements is that Qunol CoQ10 will be effective in preventing or treating symptoms of the diseases referenced in the advertisements including, breast cancer, arthritis, atherosclerosis, HIV/AIDS Alzheimer’s disease, Parkinson’s & ALS and diabetes. Citing the FDA disclaimer on the advertiser’s website, “This product is not meant to diagnose, treat, cure or prevent any disease,” CRN noted that the FDA disclaimer contradicts these express and implied claims.

As a preliminary matter, CRN addressed the advertiser’s representations regarding the discontinuance of the challenged claims.

Disease Claims. CRN stated that it appreciated the advertiser’s willingness to permanently discontinue the disease claims in its advertising, but noted that regardless of the substantiation, these types of disease-related claims, i.e., that Qunol CoQ10 will be effective in preventing or treating symptoms of the diseases referenced in the advertisements including, breast cancer, arthritis, atherosclerosis, HIV/AIDS Alzheimer’s disease, Parkinson’s & ALS and diabetes, are not permissible for dietary supplements under the Food, Drug & Cosmetic Act.

CRN also pointed out that despite the noted discontinuances, the advertising of Qunol products still includes implied claims that Qunol will lower blood pressure, including:

“CoQ10 deficiency has shown to be present in some patients with high blood pressure.”

and

“CoQ10 is not a specific high blood pressure supplement. Rather, it seems to correct some metabolic abnormality that in turn has a favorable influence on the blood pressure.”

CRN maintained that, as with the other disease claims, direct or implied claims that a product may be beneficial in the treatment of high blood pressure, is considered a claim to treat, cure or prevent disease, and, as such, should also be discontinued.

Absorption vs. Effectiveness. The Qunol homepage contains a hyperlink that states “absorption = effectiveness - why is absorption most important.” While CRN recognized that the advertiser provided substantiation for its superior absorption claims pertaining to hydrosoluble forms of

2 http://www.qunol.com/CoQ10HealthBenefits.aspxare
3 http://www.qunol.com/Default.aspx#
CoQ10 in the form of *ubiquinone*, there was no substantiation for the claim, direct or implied, that Qunol CoQ10 is more effective than other CoQ10 products. In fact, CRN noted, in two of the published articles submitted by the advertiser in support of the comparative absorption claims, the authors concluded that the data suggest superior bioavailability of hydrosoluble CoQ10 products, but state that this does not mean they are more effective. More specifically, noted CRN, the Bhagavan study cited by the advertiser stated, “Furthermore, whether such high plasma concentrations maximize the therapeutic potential of CoQ10 needs to be explored,” and the Chopra et al. study stated, “While the above findings are inconclusive as to which type of product is better…."

CRN maintained that any direct or implied claims that absorption equals effectiveness must be substantiated with competent and reliable scientific evidence. CRN added that greater absorption does not necessarily equal greater effectiveness, and these types of comparative performance claims would, at a minimum, require comparative studies with well defined clinical or biological endpoints.

*Ubiquinone vs. Ubiquinol vs. ‘Regular’ CoQ10.* CRN was further concerned by the advertiser’s reliance on studies conducted on one form of CoQ10 for claims related to a different form. CRN noted that the research provided by the advertiser appears to provide substantiation for increased absorption into plasma for “Q gel,” which the advertiser explains is the same chemical moiety as Qunol CoQ10. CRN noted that it is not clear how the advertiser quantified the results from the research to suggest “up to 300% better absorption” in the advertising, or what evidence supports the claims that “Qunol CoQ10 liquid” is 6 times better absorbed or that 100 mg of the liquid CoQ10 is equivalent to up to 600 mg of regular CoQ10.

Citing an animal study by Abdel-azim Zaghloul, et al., CRN noted that the researchers report bioavailability of a water-miscible (hydrosoluble) form of CoQ10 called *ubiquinone* (Q-gel, which the advertiser represents is the same as Qunol CoQ10) as approximately 3 times more bioavailable than the control. In this study, a water-miscible form of *ubiquinol*, the reduced form of CoQ10, was reported to be approximately 6 times more bioavailable than the control. CRN noted that the advertiser did not clarify whether “Qunol CoQ10 liquid” is a water miscible form of *ubiquinol* and not in the form of *ubiquinone*. Importantly, CRN stated, that same “6 times increase” in bioavailability of water-miscible form of *ubiquinol* was not observed in a similar study conducted in humans by Miles et al., 2002. In the Miles study, CRN noted, a 3.44 fold increase in plasma CoQ10 was observed using *ubiquinol* compared to a 1.23 fold increase using a powdered form of *ubiquinone*, which, CRN stated, cannot support a “6 times better absorbed” claim, if in fact, the advertiser is using a water-miscible form of *ubiquinol*.

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5 Citing, e.g. Schiff Nutrition Group (MegaRed Omega-3 Krill Oil), NAD/CARU Case Reports, Report # 4970 (2009)
In addition, CRN added, the label of “Qunol CoQ10 liquid” includes the claim, “6 X better than regular CoQ10.” In the above referenced study by Abdel-azim Zaghloul, et al., water-miscible *ubiquinol* was reported to be approximately 6 times more bioavailable than a powder filled capsule of *ubiquinone* used as a control. CRN maintained that, with such a wide variety of CoQ10 formulas available to consumers, it is difficult to know what the term “regular CoQ10” means to consumers. Accordingly, CRN stated that it is important to disclose what specific form of CoQ10 product is being compared, rather than grouping all of the CoQ10 products together as “regular CoQ10.” For example, CRN stated, no substantiation was provided that the water-miscible *ubiquinol* is 6 times more bioavailable than a CoQ10 suspension in oil or a powder-based tablet. Therefore, CRN argued, the advertising should specifically state what form of CoQ10 is being compared to Qunol CoQ10 when making such a quantified comparison claim.

“Doctor Recommended” Claims. CRN noted that, while the advertiser suggested that its “doctor recommended” claim is based on several physicians who recommend hydrosoluble CoQ10 softgels, it did not submit any evidence of these recommendations. To support this type of doctor opinion claim, CRN stated, NAD requires substantiation for claims in the form of “a random and statistically representative survey of doctors showing that a substantial percentage recommend the product and should be based on the actual experience of physicians in their ordinary practice.”

**Adviser’s Position:** Upon receipt of NAD’s inquiry, the advertiser informed NAD that it had voluntarily discontinued several of the claims at issue. Specifically, the advertiser stated that it discontinued all of its health claims, including claims that, “This reduces the risk of heart disease, stroke, kidney disease and dementia,” “Medically Proven Efficacy,” “Qunol reduces fasting blood glucose levels by 33%,” as well as its claims regarding the product’s ability to lower blood pressure. In addition the advertiser represented that it discontinued its “Doctor Recommended CoQ10 Formula” claim. The advertiser also stated that it modified its claim “Clinically Proven,” to read, “The hydrosoluble CoQ10 in Qunol softgels has been used in several clinical studies.”

The advertiser addressed the remaining claims at issue:

**300% more absorbable and effective**

The advertiser submitted several published and unpublished studies which, it maintained, substantiate the enhanced bioavailability of the hydrosoluble CoQ10 in Qunol.

The advertiser submitted a laboratory report from the manufacturer of Qunol substantiating its hydrosolubility (i.e., that it passes USP Dissolution Test). The advertiser also submitted reports of tests conducted on other CoQ10 softgel brands sold in the mass merchandise stores, that it maintained, indicates their lack of solubility, as shown by their lack of dissolution in the USP Dissolution Test.

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8 Citing Matrixx Initiatives, Inc., NAD/CARU Case Reports Report #5008 (May 2009).
The advertiser noted that, while the other brands tested do not claim hydrosolubility on their labels, the formula CoQ\textsubscript{10} itself, by virtue of being essentially insoluble in water, possesses very poor absorptive property upon oral administration. This poor absorption, the advertiser stated, has been shown to be enhanced several fold by reducing the particle size of the CoQ\textsubscript{10} to sub-micron size levels, thereby facilitating the formation of a Hydro-solv in water. It is well known, and scientifically documented, the advertiser stated, that increasing the hydrosolubility of highly insoluble molecules and/or reducing their physical particle size to submicron levels enhances absorption.

The advertiser added that, regarding the “Ingredient benefits vs. product benefits” issue, the CoQ\textsubscript{10} molecule has not been modified/changed in Qunol and, therefore, all benefits that have been reported in published research for CoQ\textsubscript{10}, similarly apply to the CoQ\textsubscript{10} in Qunol, perhaps even moreso, stated the advertiser, because of Qunol’s patented, enhanced absorption delivery system.

Absorption vs. Effectiveness

The advertiser stated that, contrary to CRN’s position that the superior absorption of CoQ\textsubscript{10} does not have an impact on its efficacy in terms of providing its claimed structure/function benefits, it maintained that it is well known and scientifically established that, in order to provide a benefit, a nutrient (e.g. CoQ\textsubscript{10}) must be first absorbed into systemic circulation in an adequate amount. Thereafter, it is carried to various organs and tissues for eventual uptake by the cells. Accordingly, stated the advertiser, effective/optimum blood levels of CoQ\textsubscript{10} are essential for it to provide any benefits at the cellular level.

The advertiser referenced published studies on participants with certain cardiovascular diseases and Parkinson’s Disease (to name a few) that, it maintained, have clearly shown that oral doses of CoQ\textsubscript{10} have to be escalated up until optimum blood CoQ\textsubscript{10} levels are achieved to elicit any beneficial clinical response. The relationship between the dissolution of CoQ\textsubscript{10} (in aqueous media) and its impact on absorption has been clearly established via in vitro studies, as well as in vivo human studies.

The advertiser stated that it is not claiming that other “non-soluble” CoQ\textsubscript{10} products in the marketplace are not bioavailable, but simply that the relative bioavailability of non-soluble CoQ\textsubscript{10} products is lower than that of solubilized CoQ\textsubscript{10} products, such as Qunol™ softgels, and that enhancing the absorption of the poorly soluble CoQ\textsubscript{10} leads to a more effective product. Therefore, the advertiser stated, studies (submitted in support) indicate that the Qunol™ formulation, due to its enhanced dissolution property, provides much better absorption than non-solubilized CoQ\textsubscript{10} formulations.

Addressing the distinction “whether Qunol™ Liquid CoQ\textsubscript{10} is based on Ubiquinone or Ubiquinol,” the advertiser pointed out that nowhere on its website, advertisements, or packaging is Qunol™ described as being Ubiquinol.
Addressing the claim of “6 times increase in absorption claim of Liquid Qunol™” the advertiser stated that a careful review of its labeling and packaging clearly discloses that the “6 times higher” absorption claim is based on a Caco-2 cell culture study (submitted in support). Further, stated the advertiser, the CoQ₁₀ in Qunol™ Liquid passes the USP Dissolution Test for CoQ₁₀. The advertiser cited its patents in support of the processing technology employed in enhancing the dissolution of CoQ₁₀ in Liquid Qunol and Qunol softgels.³

**Decision:** Upon receipt of NAD’s inquiry, the advertiser represented that it had voluntarily discontinued several of the claims at issue. NAD reviewed the modifications and discontinuances.

NAD found the advertiser’s discontinuance of its claims regarding blood pressure to be necessary and proper.¹⁰ Similarly, NAD found the advertiser’s discontinuance of the claims that “This reduces the risk of heart disease, stroke, kidney disease and dementia,” “Medically Proven Efficacy,” and “Qunol reduces fasting blood glucose levels by 33%.” to be necessary and proper, as there was insufficient evidence to support claims that CoQ₁₀ has been shown to provide any of these claimed health benefits.¹¹

In addition, although the advertiser maintained that several physicians’ have recommended hydrosoluble CoQ₁₀ softgels (Q-Gel®), in the absence of any survey evidence, NAD found the advertiser’s discontinuance of its “Doctor Recommended” claim to be necessary and proper.

Also, although the advertiser modified the claim, “Clinically Proven,” to, “The hydrosoluble CoQ₁₀ in Qunol softgels has been used in several clinical studies,” in NAD’s view, stating a supplement has been “used in several clinical studies” can be reasonably understood by consumers to mean that it has been studied and shown to be efficacious.¹² As there are no “clinical studies” testing the efficacy of the hydrosoluble CoQ₁₀ in Qunol Softgels, NAD recommended that this claim be discontinued. That being said, as discussed below, NAD found that the advertiser can make absorbability claims for its Qunol CoQ₁₀ products.

**The Products**

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³ The technology employed in processing liquid Qunol is described in U.S. Patent No. 6,455,072, and the technology employed in processing the CoQ₁₀ in Qunol™ softgels is described in U.S. Patents Nos. 6,056,971 and 6,300,377.

¹⁰ For example, See Burke Briant E, et al, Randomized, Double Blind, Placebo-Controlled Trial of Coenzyme Q10 in Isolated Systolic Hypertension, Southern Med J 2001;94(11)(study of 46 men and 37 women with isolated systolic hypertension were given 60 mg of CoQ₁₀ twice daily for 12 weeks. The results found that the mean reduction in systolic blood pressure of the CoQ₁₀ supplemented group was 17.8 +/- 7.3 mm Hg.)

¹¹ NAD also noted (as pointed out by CRN) that claims that Qunol CoQ₁₀ will be effective in preventing or treating symptoms of disease are not permissible for dietary supplements under the Food, Drug & Cosmetic Act.

¹² Cite Hepzone case (“NAD was concerned that consumers might misinterpret the claim that HepZone SST is “in phase II clinical trials in New York and San Diego.” First, there are no results of these “phase II” tests at this time, and there is no way to determine whether the results will be positive, negative or inconclusive. While the preliminary results of the Phase I part of the test showed some positive results, they were not significant, nor could they support any advertising claims. Under these circumstances, NAD was concerned that consumers could reasonably interpret the claim that the product is “in phase II clinical trials” to mean that there are already positive results from these studies.”).
The advertiser, Quten Research Institute ("Quten"), explained that it manufactures and markets 2 different formulas of CoQ10 supplement products, a liquid product, Qunol Liquid CoQ10, and a soft-gel product, Qunol Ultra CoQ10. Quten explained that CoQ10 supplements, which have been on the market for more than 15 years, have been known to be highly insoluble and consequently, not very absorbable. In contrast, stated Quten, both of its products are highly absorbable, and as a result, will increase the blood levels of the nutrient CoQ10. The advertiser maintained that its advertising is simply touting the greater absorbability of its products, as compared to other CoQ10 supplements on the market.

One of the studies submitted by the advertiser in support of its claims, the Bhagavan review, discussed CoQ10, its benefits and how it is absorbed and synthesized by the body. It noted that CoQ10 is a vitamin-like nutrient that is present in all human tissue and under normal conditions, cells synthesize CoQ10, and as a result, cells generally have enough CoQ10. Oxidative stress and aging, however, may result in CoQ10 deficiencies, and therefore, supplementation will help replace and restore those levels.

Absorption of the CoQ10 nutrient has been an issue because the initial CoQ10 supplements offered on the market were not well absorbed. Because of its hydrophobicity and large molecular weight, the absorption of dietary CoQ10 is slow and limited, and solubilized formulations of CoQ10 have shown enhanced bioavailability. As a result, NAD noted that several manufacturers currently advertise “absorbability” as one of the features of their CoQ10 supplements.

In support of its “greater” absorbability claims, the advertiser submitted human, in vitro and animal absorption studies conducted on both its liquid and soft-gel Qunol products. In addition, in response to NAD’s inquiry, the advertiser represented that it had modified and/or discontinued several of the claims at issue.

**Greater Absorption**

In support of its claims for greater absorption, the advertiser relied on several studies measuring the absorptive properties of its products as compared with other CoQ10 products on the market.

The Miles study compared the bioavailability of four CoQ10 supplements, (1) Li-Q10 (a liquid containing solubilized coenzyme Q10), (2) Q-Nol, the advertiser’s Q Gel product (a soft capsule containing ubiquinol, the reduced form of coenzyme Q10), (3) UbiQGel (a fully solubilized coenzyme Q10), and (4) capsulized Q10 powder.\(^{13}\) The study included 9 healthy individuals\(^ {14} \) and the plasma CoQ10 levels were measured before and after supplementation. The study recognized that “Coenzyme Q10 is strongly lipophilic, practically insoluble in aqueous solution, and has poor bioavailability in humans.”

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\(^{14}\) 12 started the study, but only 9 completed.
The results indicated that significantly increased CoQ10 concentrations were measured in those participants taking the Q-Nol product and increased concentrations, but not statistically significant, for those participants taking the Li-Q10 product.

The Chopra study was a two part study, comparing the plasma CoQ10 concentrations in the study participants, both before and after supplementation with 4 different CoQ10 formulations, 1) an oil-based capsule, 2) a powder filled capsule, 3) a tablet formulation, and 4) Q-Gel softgels (i.e., the advertiser’s product). In the first part of the study, 24 individuals, separated into 4 groups, were given the 4 different CoQ10 supplements for 3 weeks and their plasma CoQ10 levels were measured each week. In the second part of the study, 24 individuals, separated into 2 groups were given either the oil-based capsule or Q-Gel softgels for 4 weeks and their plasma CoQ10 levels were measured each week.

The results of the first part of the study indicated that the Q-Gel group showed a 6.6-fold increase over baseline values, whereas the other three groups showed a lower increase, ranging from 2.7 to 3.3. The results of the second part of the study (carried out in order to confirm the results of the first part), indicated that the increase in plasma CoQ10 was 7.37-fold for Q-Gel and 3.15-fold for the oil suspension CoQ10 supplement.

The advertiser also relied on a study from New Zealand, comparing the bioavailability of the various CoQ10 supplements on the market, Q-Gel, Radiance, Blackmores, Solgar, Kordel’s, Thompson’s, and Good Health. The study found that Q-Gel had the highest bioavailability, with Radiance and Blackmores brands the next highest. The advertiser compared the median change in plasma CoQ10 levels achieved with Q-Gel against each of the other brands tested, the results indicated that the median change obtained with Q-Gel is superior to the other brands by 182%, 256%, 289%, 331%, 339% and 421% respectively. The advertiser then took the average of these percentages and calculated 303%. Based on this, the advertiser concluded that, on average, Q-Gel delivers 303% more CoQ10 to the bloodstream than the other 6 products tested and, as such, provides a reasonable basis for its “300% more absorbable…” claim.

In addition to the human studies described above, the advertiser also cited several animal studies, that it maintained, confirmed the results. For example, the advertiser submitted a study conducted on dogs, also indicating a significantly increased plasma concentration for the dogs given the Q-Gel CoQ10 supplements. While testing conducted in animals cannot support claims for products for humans, NAD noted that the results of this study were consistent with the results of the above-discussed studies on humans.

The advertiser also submitted an in vitro study, measuring the absorption of CoQ10 in human intestinal cells. This study, the Bhagavan study, from Ohio State, measured the CoQ10

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16 The bioavailability of coenzyme Q10 supplements available in New Zealand differs markedly, NZMJ 8 October 2004, Vol 117 No 1203.
17 The advertiser also compared the CoQ10 to LDL cholesterol and total cholesterol ratio numbers achieved in the study, arriving at an average of 295% for LDL, and 303% for total cholesterol.
concentration in human intestinal cells after being exposed to 8 different CoQ10 products on the market. Two of the CoQ10 supplements in the study were the advertiser’s products; the Q-Gel soft gels and the Qunol liquid. The study recognized that human absorption studies are very costly and time consuming, and noted that this “coupled simulated digestion/Caco-2 cell model system is an effective tool for screening the digestive stability, accessibility and apical uptake of bioactive components from various products.”\(^{19}\) The reference product in this study was pure CoQ10 powder. The results of this study indicated that the amount of CoQ10 taken up by the Caco-2 cells ranged from 30 to 257 pmol/mg protein. The greatest absorption was achieved with the Hydro-Q-Sorb and Liquid Q, followed by Q-Gel softgels and ChewQ chewables. In comparison, the three tablets studied were poorly absorbed. The study assigned a value of 100% absorption to the reference product, pure CoQ10 powder, and compared to that, the advertiser’s liquid product, Liquid Q was absorbed 693%, and the advertiser’s Q-Gel softgel product was absorbed 342%. These are the results that the advertiser relies on as support for its claims of “600% more absorbable” and “6X better absorption” for the liquid Qunol, noting that the results are consistent with the human studies indicating a 300% greater absorption for the soft gel product.

Although the human studies included a relatively small number of participants, NAD noted that the advertiser provided several studies conducted on the product itself, Q-Gel, measuring the CoQ10 plasma concentrations of the participants, both before and after supplementation, all consistently indicating that supplementation with Q-Gel soft gels resulted in a significantly increased plasma CoQ10 concentration. In addition, the advertiser’s in vitro human intestinal cell study yielded results consistent with the human studies, regarding Q-Gel absorption. Based on these results, NAD concluded that the advertiser provided a reasonable basis for its claims that Q-Gel is more absorbable than other non-solubilized CoQ10 supplements on the market.

NAD next considered whether the advertiser could support its quantified “up to 300% more absorption.” Analyzing the results of the human studies, NAD noted that, (1) the Chopra study found an increased plasma CoQ10 concentration of 7.37-fold for Q-Gel as compared to an oil-based capsule, a powder filled capsule, and a tablet formulation, and (2) the study from New Zealand found a range of increased plasma CoQ10 concentrations as compared to other products on the market, ranging from 182%, 256%, 289%, 331%, 339% to 421%. The advertiser averaged these percentages and calculated an average increased plasma concentration of 303%. In addition, while NAD would not rely on the in vitro Bhagavan study on its own, to support the claims, NAD did note that this study also found a 342% increased cellular absorption of CoQ10, as compared to the reference standard, pure CoQ10 powder. Based on these studies, NAD was satisfied that human studies provided support for the advertiser’s “up to 300% more absorbable” and “up to 3X more absorbable” claim for its Qunol Q-Gel products, as compared to the non-solubilized CoQ10 products on the market. NAD recommended, however, that the advertiser make it clearer what it is comparing its product to, i.e., “what is Qunol 300% more absorbable than?” NAD found that the advertising, as written does not make it clear what the object of comparison is.

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19 Id
**Liquid Qunol versus Qunol Soft-Gel**

The advertiser markets two different forms of CoQ10, liquid and soft-gel. Both the liquid and soft-gel products contain the same solubilized CoQ10, just in different formulations, i.e., liquid suspension and gel. The advertising claims that Liquid Qunol is 600% more absorbable, and Qunol Soft-Gels are 300% more absorbable. As discussed above, NAD found that based on the human studies on the Qunol soft gels product, the advertiser provided support for its claims of “up to 300% greater absorption.” The claims for greater absorbability for its liquid Qunol product, however, are solely based on *in vitro* testing on human intestinal cells.

This raised two concerns. First, the claims for the liquid Qunol product are based only on *in vitro* testing. While NAD recognized that the results of the *in vitro* testing were consistent with the human testing regarding Qunol Soft-Gel absorption, and can help provide *supporting* evidence for the human testing, NAD was concerned about claims for a product for humans based solely on laboratory testing.

Second, the advertising includes different absorption claims for the two different products, i.e., 300% more absorbable for the Qunol Soft-gels and 600% more absorbable for the Qunol liquid, which NAD found may be confusing to consumers.

NAD determined that the *in vitro* testing alone is insufficient to establish that the liquid Qunol product will reach the claimed “up to 6X better absorption” in humans. While the *in vitro* study suggested that the liquid Qunol was absorbed 6X more than the reference standard and 2X more than the soft-gels, there was no evidence that this would occur in the human body. In fact, NAD noted, there was no evidence that it is even possible to achieve the absorption concentrations achieved *in vitro*, in humans. Consequently, NAD recommended that the advertiser discontinue its “up to 6X better absorption” claims, and limit its claims to “up to 3X” and “up to 300% more absorption” as established in the human studies it provided.20

**Absorption vs. Effectiveness**

CRN argued that the advertising inaccurately equates absorption with effectiveness, noting that even if the advertiser could support claims that its Qunol products are more absorbable than other CoQ10 products on the market, such evidence does not support claims for greater effectiveness.

The advertiser, on the other hand, argued that in order for CoQ10 to have *any* beneficial effect, it must first be adequately absorbed by the body. As discussed above, the advertiser provided

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20 NAD recognized that the human studies provided by the advertiser only studied the soft gel product, and not the liquid product. Despite this, NAD found no evidence to suggest that the liquid Qunol product would be absorbed any differently in humans, since both products contain the same solubilized CoQ10 and, in fact, the evidence from the *in vitro* study suggested that the liquid Qunol would have greater absorption than the Qunol soft gel. Accordingly, NAD found that the advertiser could rely on the human studies on its soft gel product to support absorbability claims for its liquid Qunol product.
support for its claims that its Qunol CoQ10 supplements are, in fact, absorbed, moreso than competing CoQ10 supplements available on the market. The advertiser maintained that to the extent its product is more absorbable than competitive, less absorbable CoQ10 supplements, it will provide greater efficacy, or at least has the potential to do so.

While there was no evidence that Qunol CoQ10 supplements are any more effective than other CoQ10 supplements, NAD concluded that the advertiser could support claims that clearly explain its position, i.e., that the greater absorbability of Qunol products could translate to greater effectiveness. NAD reasoned that as the advertiser argued, CoQ10 must first be absorbed to have any effectiveness, and since the absorbability of CoQ10 has been an issue in the industry, the advertiser could make claims touting the improved absorbability of its Qunol products, and that such greater absorbability has the potential to improve effectiveness.

NAD cautioned, however, that the advertiser should be careful to avoid any claims that equate absorbability with effectiveness, as well as claims conveying a message that the advertised products are more effective, because they are better absorbed. Accordingly, NAD recommended that the advertiser discontinue statements that currently appear on the advertiser’s website such as, “Absorption = Effectiveness” and “Qunol Ultra Co Q10 up to 300 times more effective.”

Conclusions: NAD found the advertiser’s discontinuance of its health claims, including claims that, “This reduces the risk of heart disease, stroke, kidney disease and dementia,” “Medically Proven Efficacy,” “Qunol reduces fasting blood glucose levels by 33%,” as well as its claims regarding the product’s ability to lower blood pressure to be necessary and proper. Similarly, NAD found the advertiser’s discontinuance of its “Doctor Recommended CoQ10 Formula,” to be necessary and proper.

NAD found that the advertiser’s modification of its claim “Clinically Proven,” to read, “The hydrosoluble CoQ10 in Qunol softgels has been used in several clinical studies,” could be reasonably understood by consumers to mean that the product has been proven efficacious in clinical studies, an unsupported claim, and therefore, NAD recommended that it be discontinued.

NAD found that the advertiser provided a reasonable basis for its claims that its Qunol soft gel product is “up to 300% more absorbable...” but recommended that the advertiser clarify the point of comparison, i.e., exactly what Qunol is “up to 300% more absorbable” than.

NAD, however, recommended that the advertiser discontinue its claim that Liquid Qunol is “Up to 6X better absorption than regular CoQ10.” as well as the claim that “100 mg Qunol Liquid CoQ10 = up to 600 mg regular CoQ10.” since these claims are based solely on an in vitro study.

Lastly, NAD recommended that the advertiser discontinue its claims that equate the absorption of Qunol with effectiveness, including the claims stating “Absorption = Effectiveness” and “Qunol Ultra Co Q10 up to 300 times more effective.” NAD, however, found that the advertiser could support claims clearly stating its position, i.e., that the greater absorption of Qunol products may result in improved effectiveness, because in order to have any effectiveness, CoQ10 must first be adequately absorbed into the body.
Advertiser’s Statement: Quten Research Institute appreciates the NAD’s review of the scientific literature underlying the claims for Qunol Liquid CoQ10 and Qunol Ultra CoQ10. Quten is pleased with the NAD’s conclusion that the products provide a meaningful benefit to consumers and that Qunol Ultra CoQ10 is “up to 300% more absorbable” than other types of CoQ10. Quten respectfully disagrees with the NAD’s conclusion regarding the claim that Qunol liquid CoQ10 provides “up to 6x better absorption.” Quten will appeal this portion of the NAD’s decision to the National Advertising Review Board pursuant to Section 3.1 of the NAD/NARB Procedures. Although Quten stands behind all of its advertising claims, it will take into account the NAD’s other recommendations in its future advertising. (#5113 MBL, closed 12/03/2009).