Dietary Supplements Attacked by the Media

By William Faloon

The media has launched an assault against healthy lifestyles and some popular dietary supplements. The public has been thrust into a state of confusion by these frenzied media reports that contradict long-established scientific principles.

I am impressed by how quickly Life Extension members picked up on the errors contained in the studies used to ridicule those who practice healthy living.

The outrage over these biased reports was not limited to Life Extension members. The front page of the Wall Street Journal carried a scathing report about how the Federal Government issued misleading press releases that gave the media the green light to discredit alternative approaches to disease treatment. According to the Wall Street Journal:

“Design problems in all the trials means the results don't really answer the questions they were supposed to address. And a flawed communications effort led to widespread misinterpretation of the results by the news media and the public.”

What you are about to read might at first seem unbelievable. Please remember, however, that the studies we describe were conducted by mainstream doctors who know virtually nothing about natural ways to prevent and treat disease.

As you will also find out, many of the doctors who designed and authored these flawed studies received financial compensation from the very pharmaceutical companies that stood to gain the most by deriding low-cost natural approaches to disease prevention.

**Media says: Eat all the fat you want**

Does eating a low-fat diet reduce the risk of contracting common diseases? The media answered this question by boldly proclaiming that there is no benefit to women eating a low fat diet. According a lead article in the Washington Post:

“Low-fat diets do not protect women against heart attacks, strokes, breast cancer or colon cancer.”

The study that this headline story was based on, however, failed to differentiate between health-promoting fats (such as monounsaturated and omega-3 fats) and lethal trans fats. It was long ago established that over-consumption of trans fats is related to atherosclerosis, cancer, and chronic inflammation. Furthermore, there was no attempt to measure the balance of omega-3 and omega-6 fatty acids.
Most Western diets contain an abundance of omega-6 fatty acids (e.g., corn, safflower oils) and completely inadequate levels of omega-3 fatty acids (such as fish oil, flaxseed, and walnut oils).

The “excuse” some researchers gave when confronted with these flaws was that when the low-fat studies were designed, doctors did not know the difference between friendly and deadly fats. The facts are that when these studies were designed, there was an abundance of published scientific data to show that friendly fats like olive oil, flax oil, and fish oil conferred life-saving benefits while trans fats were proven killers.

Researchers also were unable to rigorously monitor whether or not the participants actually followed low-fat diets. Food-intake questionnaires were used, which are notoriously unreliable indicators of what is really eaten.

In what is perhaps the most outrageous defect in these studies, only 1 in 7 women actually achieved the low-fat diet threshold! Specifically, only 14.4% of the “low-fat” group really followed a low-fat diet. Furthermore, the average reduction in total fat intake in the “low-fat group” was only 8.2% (with just a 2.9% decrease in saturated fat intake). Assuming that this paltry 8.2% figure is accurate (i.e., that the food questionnaires were completely accurate), this number does not come close to the percentage of fat-calorie reduction other studies have shown is needed to reduce disease risk.

These flaws rendered this multimillion-dollar low-fat diet study worthless. This did not stop major newspapers, however, from featuring articles on their front pages stating that reduced-fat diets provide no health benefits.

MEDIA SAYS CALCIUM DOES NOT PROTECT BONES

One of the most controversial media stories dealt with a study that supposedly showed that women who took calcium and vitamin D supplements did not obtain any protection against hip fracture.

We at Life Extension initially thought this negative finding was because the active group was not given magnesium, zinc, manganese, and other nutrients that are essential to maintaining optimal bone density.

When we got our hands on the study itself, we were startled to find that the women in the study who actually took their calcium and vitamin D supplements suffered 29% fewer hip fractures. This was contrary to what the headlines said. It turned out that the media believed the government’s negative press release and obviously did not read the actual scientific study.
Many study subjects failed to take their calcium-vitamin D supplements

In this study to evaluate the efficacy of calcium and vitamin D compared to placebo, it was startling to learn that many women in the active arm did not take their calcium-vitamin D supplements! According to the study report, about 40% of the women assigned to take calcium and vitamin D did not achieve a standard rate of compliance with their supplements!

When the entire study was tallied, the women in each group (active and placebo) officially remained in their respective group, whether or not they actually followed the study protocol. This meant that women in the active group (the one given the calcium-vitamin D supplements) were counted as having taken the calcium-vitamin D, whether they really took the supplement or not. According to the scientists who conducted this study:

“Participants were followed for major outcomes, regardless of their adherence to the study medication…”

The “study medication” mentioned above is the calcium-vitamin D supplement. The fact that a study could be published in a medical journal “regardless” of whether the participants actually took the active ingredient defies logic. The application of common sense would invalidate the findings of this study, regardless of what statisticians might argue.

Placebo group allowed to take calcium and vitamin D

Further confounding the study results were previously unheard-of rules that allowed the placebo group to take multi-vitamin, calcium, and vitamin D supplements on their own if they wanted. It turned out that many in the placebo group were taking calcium and vitamin D. According to the study design, since they were part of the placebo arm, they were officially not taking calcium-vitamin D supplements, even though many of them were indeed taking calcium-vitamin D.

The fact that the placebo group was freely allowed to take multivitamins, calcium and vitamin D meant that many of the placebo participants may have consumed more bone-protecting nutrients (including boron, magnesium, zinc, and manganese) than the active group (who were supposed to be taking only calcium and vitamin D). By failing to separate who was really taking bone-protecting supplements, it was impossible draw a scientific conclusion, yet the media boldly asserted that there was no difference in the hip fracture rate in the group assigned the calcium-vitamin D supplements (many of whom were not taking their supplements) as compared to the placebo group (many who were consuming calcium, vitamin D, and other bone-protecting supplements).
Bone building hormones and drugs also permitted

Not only was the placebo group allowed to take their own calcium, vitamin D, and other bone-maintenance supplements, but both groups were also allowed to take drugs (bisphosphonates and calcitonin) and hormone therapies that are known to prevent bone loss and restore bone density. In this study that the Federal government spent over $10 million funding, virtually anything was allowed.

Media grossly misleads public

While the study itself was badly flawed, the media distortion of the findings is nothing short of abominable. Front-page news stories declared calcium-vitamin D supplements had been proven worthless, yet the actual study stated:

“Women receiving calcium with vitamin D supplements had greater preservation of total-hip bone mineral density…”

“Among women who were adherent (i.e., those who took at least 80 percent of the study medication), calcium with vitamin D supplementation resulted in a 29 percent reduction in hip fracture…”

“The effect of calcium with vitamin D might require higher doses of vitamin D than were used…”

“It is also plausible that there was a benefit only among the women who adhered to the study treatment.”

As you will read in the June 2006 issue of Life Extension magazine, there are even more serious flaws in this calcium-vitamin D study than what I just described, but it is safe to state that this may have been one of the most poorly designed studies in the history of modern medicine. This did not stop the media from turning it into one of the main headline news stories of the day.

Millions of American women will discard their calcium and vitamin D supplements based on these false and misleading headlines. This is great news for pharmaceutical companies that sell expensive drugs to treat osteoporosis.

Biased attack on glucosamine

The next victim of the media’s witch hunt was glucosamine, which was one of several agents tested as a treatment for osteoarthritis of the knee.

The media’s deceptive stories were based on a study of people with mild to severe knee pain who were given a form of glucosamine not normally found in dietary supplements. Some participants received this form of glucosamine by itself, while others were given chondroitin sulfate by itself, a combination of glucosamine and chondroitin, or the drug Celebrex®.
The results of this study were encouraging, but the media distorted the findings in a way that made it appear that glucosamine-chondroitin supplements were of little value. A number of media outlets proclaimed that arthritis sufferers were wasting their money by taking glucosamine. While this made compelling headlines, it did not accurately convey what was written in the actual study.

The findings from the actual scientific study made it clear that glucosamine and chondroitin taken together were effective in those with moderate to severe arthritis of the knees. 59

**MEDIA MAY NOT HAVE READ GLUCOSAMINE STUDY**

The media appears to have relied on a biased editorial that accompanied the actual scientific report on glucosamine. For instance, the *New York Times* said the following about this arthritis study:

“No effect was found for glucosamine, chondroitin, or the combination of both.” 60

Yet on page 804 of the study (which was published in *New England Journal of Medicine*), the following was stated about patients with moderate to severe arthritis of the knee who took glucosamine-chondroitin therapy:

“...combined treatment was significantly more effective than placebo” 59

The actual study went on to say that in those with moderate to severe arthritis, the combination of glucosamine-chondroitin resulted in a 24.9% to 26.4% improvement in pain relief. This result exceeded the 20% response to treatment measurement that the scientists themselves stated would prove efficacy. 59

As far as reversing the structural damage inflicted to the knee by osteoarthritis, the scientists stated:

“Treatment with chondroitin sulfate was associated with a significant decrease in the incidence of joint swelling, effusion, or both.” 59

In their concluding remarks, the scientists stated:

“Our finding that the combination of glucosamine and chondroitin sulfate may have some efficacy in patients with moderate-to-severe pain is interesting, but must be confirmed by another trial.” 59

As anyone who understands the English language can read, even this different form of glucosamine, when combined with chondroitin sulfate, demonstrated efficacy in patients most in need, i.e., those with moderate-to-severe pain! The media overlooked these clearly written findings in their haste to viciously attack glucosamine and chondroitin dietary supplements.
**Better than Celebrex®**

One of the arms in this arthritis study was given 200 mg a day of Celebrex®, an FDA-approved arthritis drug.

In patients with moderate to severe knee pain, however, the only treatment that showed significant benefit was glucosamine-chondroitin.

The media, however, chose to tout the mediocre benefits that Celebrex® showed in this study. For instance, in a widely distributed Associated Press story, the following was stated about Celebrex®:

> “The drug Celebrex did reduce pain — 70 percent reported improvement — affirming the study’s validity.”

The inclusion of Celebrex, in fact, did not affirm the study’s validity considering that 60 percent of the placebo group also reported improvement. The authors of this study stated that compared to placebo, Celebrex® was “not significantly better.”

In the concluding remarks, these scientists stated:

> “However, even the effects of celecoxib (Celebrex®) were smaller than those seen in other studies.”

The media exaggerated the benefits of Celebrex while vilifying glucosamine-chondroitin, carrying on a long tradition of bias against dietary supplements.

**The arthritis study’s disappointing findings**

The data that caused these negative media stories involved study subjects with mild knee pain. The scientists noted that in these patients, “differences between placebo and the various agents were relatively small.”

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**Conflicts of Interest**

The *New England Journal of Medicine* recently enacted a policy of mandating disclosure of potential financial conflicts of interest amongst the authors of the studies it publishes. The reason for this was past instances of questionable articles supporting the safety-efficacy of drugs authored by doctors who were financially beholden to pharmaceutical companies that made the drugs.

What follows are the potential conflicts of the authors of the negative glucosamine study as reported by the *New England Journal of Medicine*:

> “Drs. Bingham, Brandt, Clegg, Hooper, and Schnitzer report having received consulting fees or having served on advisory boards for McNeil Consumer and Specialty Pharmaceuticals. Drs. Brandt, Moskowitz, Schnitzer, and Schumacher report having received consulting fees or having served on advisory boards for Pfizer. Dr. Brandt reports having equity interests in Pfizer. Drs. Moskowitz and Weisman report having received lecture fees from Pfizer; Dr. Brandt, lecture fees from McNeil Consumer and Specialty Pharmaceuticals; Drs. Bingham, Clegg, Hooper, Jackson, Molitor, Sawitzke, and Schnitzer, grant support from Pfizer; and Dr. Bingham, grant support from McNeil Consumer and Specialty Pharmaceuticals. Dr. Brandt reports having received royalties from books related to osteoarthritis. Dr. Moskowitz reports having served as an expert consultant for Pfizer.” — pp. 807

Arthritis drugs are (or have been) huge money makers for the pharmaceutical companies. These same companies have paid monies to doctors who designed, oversaw, and authored the *New England Journal of Medicine* study and the negative editorial about glucosamine. Readers can make their own determination if this represents frank bias or, at a minimum, a disingenuous approach to scientific research.
As compared to placebo, here were the pain score percentage point improvements for overall groups within this study:\textsuperscript{59}

<table>
<thead>
<tr>
<th>Therapy</th>
<th>Improvement in Primary Pain Score</th>
<th>Improvement in Secondary Pain Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucosamine HCL only (note this is not glucosamine sulfate)</td>
<td>3.9%</td>
<td>3.7%</td>
</tr>
<tr>
<td>Chondroitin sulfate only</td>
<td>5.3%</td>
<td>6.6%</td>
</tr>
<tr>
<td>Glucosamine HCL plus chondroitin sulfate</td>
<td>6.5%</td>
<td>8.7%</td>
</tr>
<tr>
<td>Celebrex\textsuperscript{®}</td>
<td>10%</td>
<td>10.4%</td>
</tr>
</tbody>
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The scientists who conducted this study appropriately noted that only three of the above changes were significant overall. Furthermore, for the primary outcome in the combined glucosamine + chondroitin group, the results were very close to reaching statistical significance. For the secondary outcome, it did reach significance!

The media misinterpreted these findings and used them as ammunition to attack the efficacy of glucosamine and chondroitin supplements.

**THE ENCOURAGING FINDINGS FROM THE ARTHRITIS TRIAL**

As noted earlier, significant benefits were seen in patients with *moderate to severe* arthritis of the knee in the *glucosamine-chondroitin* group. Compared to placebo, the pain score percentage point improvements in the moderate to severe arthritis group were as follows: \textsuperscript{59}

<table>
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<tr>
<th>Therapy</th>
<th>Improvement in Primary Pain Score</th>
<th>Improvement in Secondary Pain Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucosamine HCL only (note this is not glucosamine sulfate)</td>
<td>11.9%</td>
<td>17.1%</td>
</tr>
<tr>
<td>Chondroitin sulfate only</td>
<td>7.1%</td>
<td>10%</td>
</tr>
<tr>
<td>Celebrex\textsuperscript{®}</td>
<td>15.1%</td>
<td>18.1%</td>
</tr>
<tr>
<td>Glucosamine HCL plus chondroitin sulfate</td>
<td>24.9%</td>
<td>26.4%</td>
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</tbody>
</table>
In patients with moderate to severe knee pain, Celebrex® provided modest relief, whereas glucosamine-chondroitin showed significant reductions in pain scores. It is interesting that Celebrex® was not criticized by the media, even though it failed to produce the expected results in this sub-group of patients suffering with moderate to severe pain.

**Wrong form of glucosamine used**

A troubling flaw in this study is that the wrong form of glucosamine was given to the study subjects. Glucosamine sulfate is the most prevalent form of glucosamine used in dietary supplements. Most of the studies showing significant efficacy used glucosamine sulfate, but the form used in the *New England Journal of Medicine* study was glucosamine hydrochloride.

Since the study subjects received glucosamine hydrochloride, they were not obtaining the joint-protecting benefits conferred by the sulfur found in the “sulfate” part of the glucosamine compound. The anti-arthritis benefits of sulfur are so well documented that many arthritis patients find relief with a low-cost supplement called MSM (methylsulfonylmethane), which is a concentrated source of sulfur. The anti-arthritic properties of SAMe (s-adenosyl-methionine) are also thought to be related to its high sulfur content.

In this *New England Journal of Medicine* study that made headline news around the world, the subjects taking glucosamine only were getting no supplemental sulfur. Even the group getting the glucosamine and chondroitin was only getting a small amount of sulfur (from the chondroitin sulfate only).

**Why the media attacked glucosamine**

In an editorial appearing in the same issue of the *New England Journal of Medicine*, glucosamine was harshly criticized. It was obviously a lot easier for the media to echo one doctor’s condemnation than to take the time to read the actual study itself.

This one doctor, by the way, receives consulting fees from Pfizer and Merck. In fact, a number of the authors of the glucosamine study published in the *New England Journal of Medicine* receive compensation from big pharma, mostly from Pfizer, which is the maker of Celebrex®. None of the study’s authors had an economic interest in glucosamine or chondroitin. Some in alternative medicine have said this is equivalent to having an opposing team’s referees dictate the outcome of a sporting event.

What most people don’t realize, however, is that it is not the obligation of the media to provide accurate reporting. The media is responsible for generating profits for its shareholders, which means they have to grab the public’s attention with sensational headlines that sell newspapers, TV viewing time, etc.

Reporting on the positive parts of the *New England Journal of Medicine* study would not have motivated many people to buy a newspaper. After all, there are dozens of studies substantiating the anti-arthritic properties of glucosamine sulfate and chondroitin sulfate. One more new study is hardly a newsworthy event.
There are now millions of Americans using glucosamine-based dietary supplements. These are the seventh most popular dietary supplement sold in the United States. There are over 20 million Americans affected by osteoarthritis. So when the largest newspaper in the United States ran the headline, “Two Arthritis Drugs Found To Be Ineffective,” they knew it would catch a lot of attention. The fact that glucosamine and chondroitin were labeled as “drugs” is an indication of how little time this newspaper spent evaluating the actual study.

HOW EFFECTIVE IS GLUCOSAMINE-CHONDROITIN?

In previous issues of Life Extension magazine, we have discussed the studies indicating a significant benefit to arthritic patients who take glucosamine sulfate and chondroitin sulfate. It is because of these successful earlier studies that this latest study published in the New England Journal of Medicine was conducted.

While glucosamine-chondroitin have documented efficacy, many arthritis sufferers need to take a broader approach to relieving inflammation, immobility, and chronic pain. Fish oil, for instance, has been shown to help reduce pro-inflammatory eicosanoids such as prostaglandin E2 and leukotriene B4, along with pro-inflammatory cytokines such as TNF-alpha and IL-1b. These inflammatory factors play a major role in degenerative joint disease. Over the past 10 years, we have published findings showing benefits when combinations of fish oil, borage oil, glucosamine, and other nutrients are taken together.

MEDIA TRIES TO BURY SAW PALMETTO

More than 20 published studies show that saw palmetto alleviates symptoms associated with benign prostate disease such as frequent urination, low urine stream, and a feeling of not completely emptying the bladder.

A recent study however, found saw palmetto to be ineffective in men with moderate-to-severe benign prostate hypertrophy. As a result of this one study, the media declared saw palmetto useless.
The doctors who conducted this negative saw palmetto study received financial compensation from **Merck** (which makes Proscar®), **GlaxoSmithKline** (which makes Avodart®), and **TAP Pharmaceuticals** (which makes Lupron®). Proscar and Avodart are drugs that directly compete against saw palmetto, whereas Lupron is used mostly by men who develop prostate cancer.

Some in the alternative medical community have cried “foul,” in as much as the doctors overseeing this negative saw palmetto study received financial compensation from the same pharmaceutical companies that stood to gain the most from discrediting non-prescription herbal therapies such as saw palmetto.

**FLAWS IN SAW PALMETTO STUDY**

One of the defects of the negative saw palmetto study is that it evaluated men who had more advanced prostate disease than did most of the participants in the favorable saw palmetto studies. In the numerous European studies that documented saw palmetto’s efficacy, most of the men evaluated were considered to have moderate prostate disease. The study used to attack saw palmetto, on the other hand, looked at men with moderate-to-severe prostate disease. Researchers long ago determined that men with moderate-to-severe benign prostate disease need aggressive therapy to achieve effective relief. This is why recent studies showing positive benefit to herbal prostate remedies have used saw palmetto combined with nettle root.142,146 This fact raises questions as to why so much money was spent funding a study of men with significant prostate disease using only saw palmetto, when European doctors prescribe combination herbal therapies to treat benign prostate disease.

Another flaw of this study is that the group assigned the saw palmetto had more pronounced prostate disease than did the placebo group. For instance, the group receiving saw palmetto had a BPH Impact Score that was statistically significantly worse than the placebo group at baseline. Whether these baseline differences had an impact on the study’s outcome is unknown. By placing men with more severe prostate disease in the saw palmetto group, however, the study was biased against saw palmetto from the beginning.

**WHY THIS STUDY IS IRRELEVANT TO AGING MEN TODAY**

European doctors use various combinations of pygeum, nettle root, beta-sitosterol, saw palmetto, and other herbs to treat benign prostate disease. Despite numerous scientific studies...
indicating that treatment of prostate enlargement should include a combination of herbal extracts, the doctors who designed the one recent negative study choose to test saw palmetto in isolation.

Based on evidence that prostate disease is caused by several different factors, it would appear that the recent study that used only saw palmetto to treat men with moderate-to-severe prostate disease was designed to fail. The study therefore has no relevance to men taking combination supplements that provide nettle root (\textit{Urtica dioica}), pygeum, beta-sitosterol, and other plant extracts that have proven efficacy in dozens of published scientific studies.\textsuperscript{151-181}

It is important to also note that this is only one study of a relatively small group of men with moderate-to-severe prostate enlargement who were only allowed to use saw palmetto. Ten times as many men with varying degrees of prostate disease have participated in other studies that showed even saw palmetto taken by itself to be highly effective.\textsuperscript{121-141}

**EXPOSING THE RECENT MEDIA ATTACK AGAINST DIETARY SUPPLEMENTS**

Over the past several months, the media has questioned the efficacy of several popular dietary supplements. In the upcoming June 2006 issue of \textit{Life Extension} magazine, we dissect these negative media reports down to the bone to reveal the hard scientific facts.

In doing so, we expose the absurdity of the headline-hungry media making proclamations such as “\textit{another natural remedy bit the dust}” when describing the recent glucosamine study. We also reveal the inappropriateness of conventional doctors, with little knowledge about the proper use of nutrients, but with strong financial ties to the pharmaceutical industry, conducting studies that contain so many flaws that their findings are largely irrelevant.

Members of the \textit{Life Extension Foundation} discover the science behind the headlines in order to avoid being victimized by the medical establishment’s ominous propaganda machine.

For longer life,

William Faloon

PS.- At the beginning of this letter, I stated that the front page of the \textit{Wall Street Journal} featured an article stating:

\textit{“Design problems in all the trials means the results don’t really answer the questions they were supposed to address. And a flawed communications effort led to widespread misinterpretation of the results by the news media and the public.”}\textsuperscript{1}

It is important to note that like other media outlets, the \textit{Wall Street Journal} (in other articles) regurgitated the same negative reports about dietary supplements as did the \textit{New York Times, Washington Post, Associated Press}, et al.
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