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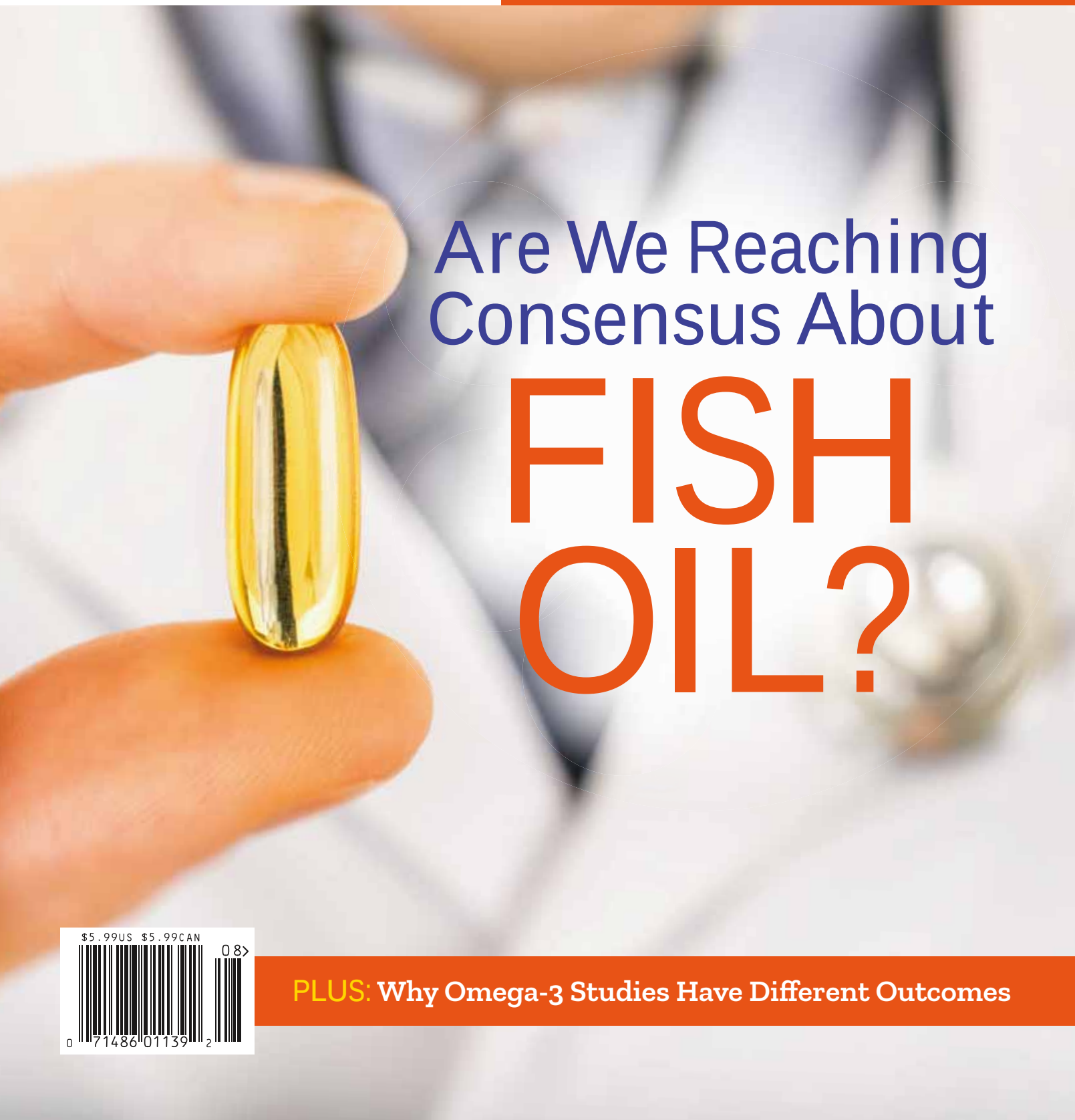
FEATURE ARTICLES



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Are We Finally Reaching Consensus About Fish Oil ?

Consumer access to fish oil has more to do with federal court rulings than findings from human studies

WILLIAM FALOON

In **2019**, the **FDA** sought the advice of an expert panel to review new data about a **fish oil** drug.

By a vote of **16-0,** the panel recommended that the **FDA** allow broader claims about its **ability to reduce cardiovascular** risks.

In **December 2019**, the **FDA** acted on this recommendation by expanding the "approved use" of this **fish oil** drug to reducing risk of **heart attack**, **stroke,** and **death** in high-risk patients.[1]

This decision was largely based on a study published in the ***New England Journal of Medicine*** showing remarkable benefits in people taking *high* doses of a **fish oil drug** that consisted of the **EPA** omega-3 fraction.[2]

Compared with placebo, there was a **25%** reduction in a composite of cardiovascular death, nonfatal myocardial infarction, nonfatal stroke, coronary stents/bypass surgeries, or unstable angina in the **fish oil** drug group.

The study observed several other benefits including:[2]

- Cardiovascular death reduced by **20%**
- Fatal or nonfatal heart attacks reduced by **31%**
- Fatal or nonfatal stroke reduced by **28%**
- Urgent or emergency coronary revascularization reduced by **35%**
- Hospitalization for unstable angina reduced by **32%**

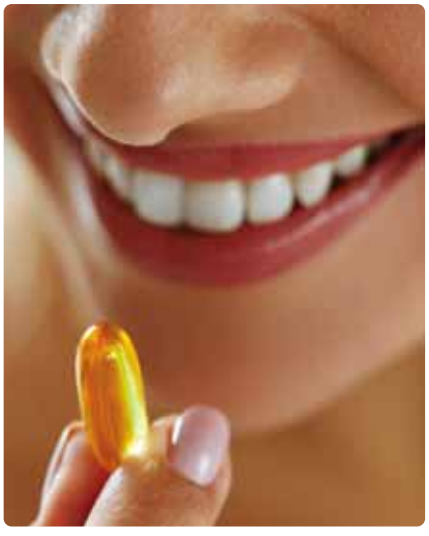
This **fish oil** is marketed to doctors as a **drug** that lowers **triglycerides** without raising **LDL** cholesterol.[3]

To the physician, this may sound appealing compared to a competitor fish oil drug that contains both **EPA** *and* **DHA**.

What troubles us, however, is that patients taking the **EPA-only** fish oil drug (Vascepa®) are unlikely to take other fish oil supplements. This ignores the critical role of the **DHA** component of the **omega-3** family on life-sustaining processes, especially **brain** and **eye** health.

The estimated out-of-pocket cost, assuming no insurance coverage, is over **$300** a month for this **EPA-only** fish oil drug. This is about **seven times *higher*** than what a comparable amount of **EPA+DHA** can be obtained for when using **dietary supplements**.

This editorial describes **legal battles** that took place over decades regarding **fish oil**, and introduces new data that corroborate the benefits of consuming ***higher*** omega-3 potencies.[4]



Many of you may take for granted your ability to purchase affordable **fish oil** supplements, but it was not always this way.

On **February 26, 1987**, the **FDA** conducted an armed raid against **Life Extension®**.[5]

The **FDA** seized our **fish oil** and brochures describing fish oil's potential to reduce cardiovascular risk.

We fought a multi-year legal battle that resulted in the government dismissing all charges against **Life Extension®**, marking the first time in the FDA's 88-year history that it has been forced to give up on a criminal prosecution.

Seven years later, Congress passed legislation that allowed consumers to access a variety of affordable dietary supplements.[6]

This helped curb the FDA's appetite for overly aggressive and frankly police-state-like enforcement actions. The FDA nonetheless continued to **censor** lifesaving data about **fish oil** and other healthy foods (such as walnuts and cherries).[7,8]

This prompted another lawsuit filed in **1994** by Durk Pearson and Sandy Shaw that sought to force the FDA to allow the following health claim on fish oil supplement labels:[9]

> ***"Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease."***

The FDA rejected this one-sentence claim, and multi-year litigation ensued based on scientific and constitutional grounds.

The **FDA** contended this health claim was not adequately backed by scientific studies and that the agency had the legal authority to ban these kinds of health claims.

After seven years of extensive litigation, the FDA capitulated and said it would permit the following claim:[9]

> ***"Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease. FDA evaluated the data and determined that although there is scientific evidence supporting the claim, the evidence is not conclusive."***

Challenging FDA's Restricted Health Claim

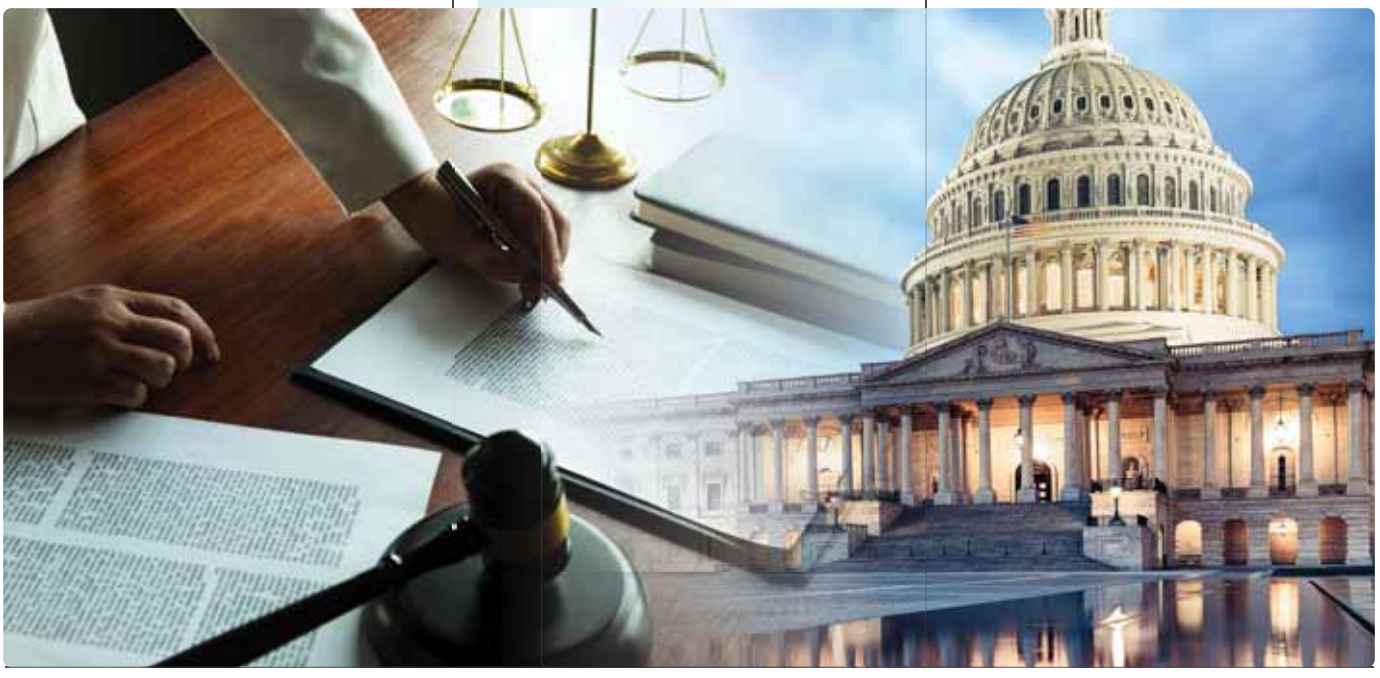
The FDA's compromise claim that the evidence was "***not conclusive***" did not satisfy us. We viewed the scientific literature back then as providing evidence that consuming fish or fish oil could lower **heart attack risk**—the nation's leading killer.

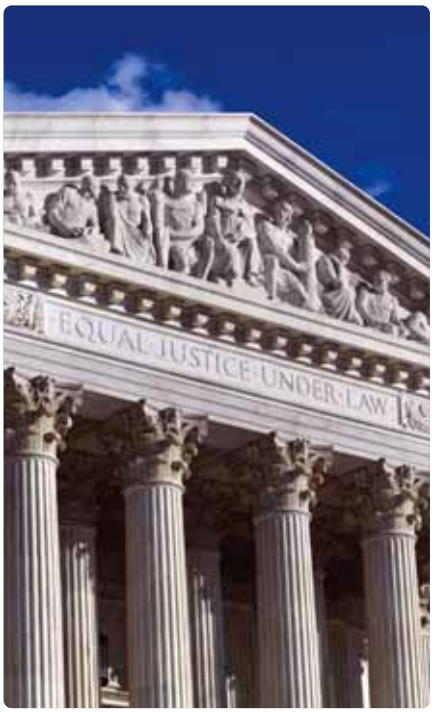
Life Extension® and **Wellness Lifestyles, Inc.** filed a health-claim petition against the FDA on June 23, 2003. The petition urged the FDA to allow the following revised claim:

> ***"Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease."***

To substantiate this position, a document enumerating the **scientific studies** backing the benefits of **omega-3** fatty acids was filed, along with arguments supporting the **constitutional** right to disseminate truthful, non-misleading information.

Everything I am describing has to do with what "words" the **FDA** allows to be on a fish oil label.





FDA Partially Capitulates

On September 8, 2004, the FDA decided to allow an expanded health claim on products containing the omega-3 fatty acids **EPA** and **DHA** as follows:

> ***"Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease."***[10]

The **FDA** went on to recommend that consumers not exceed more than **3,000 mg** per day of EPA and DHA omega-3 fatty acids, with no more than **2,000 mg** per day derived from **dietary supplements**.[11]

Life Extension® argued that many studies show that ***higher*** amounts of **EPA** and **DHA** are often needed to obtain benefits, such as reduction of **triglycerides**.[12,13]

Our position continues to be vindicated in studies showing benefits when ***higher*** potencies of **omega-3s** are consumed.

FDA Suffers Major Defeat in Federal Court

The FDA strictly ***regulates*** what drug makers are permitted to say about their products. Until recently, what could be said was limited to what the FDA allowed.

A major victory over **FDA** censorship occurred when a maker of prescription-drug **fish oil** sued the **FDA** to make a health claim about fish oil's potential to reduce **cardiovascular disease** risk.[14]

The FDA insisted it was **illegal** for the maker of this **fish oil drug** to state a **coronary disease** prevention claim until the FDA said so.

After years of costly litigation and thousands of pages of documents produced, a **federal court** ruled that a qualified health claim could be made for a **fish oil drug** called Vascepa®.

The court based this **2015** ruling on the facts that:

- The claim is truthful and non-misleading.
- FDA accepted this phrasing elsewhere in its regulatory labyrinth.
- The First Amendment to the U.S. Constitution allows it.

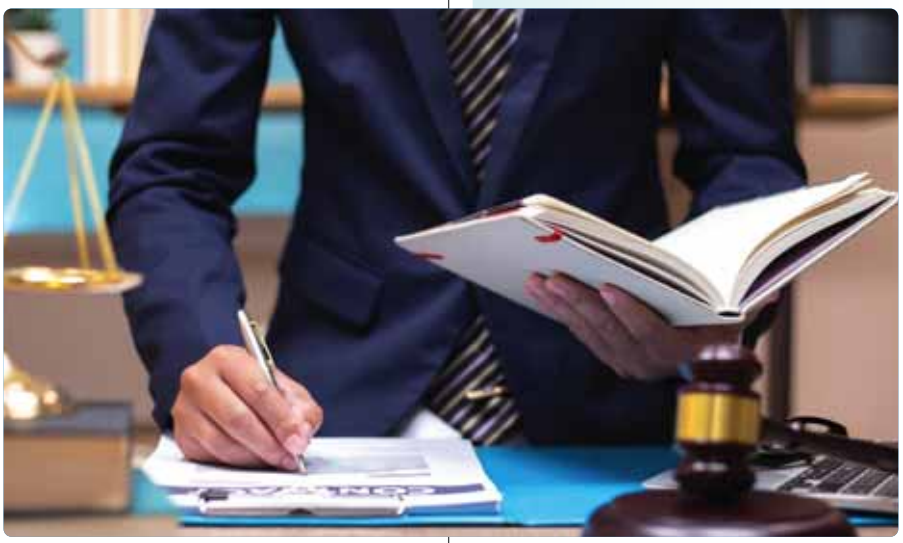
Here is the revised claim the federal court ruled could be made to doctors about this fish oil drug in **2015**:[14]

> ***"Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease. Vascepa® should not be taken in place of a healthy diet and lifestyle or statin therapy."***

After years of protracted disagreement that led to full-blown litigation, the above statement is the primary outcome of this legal victory over **FDA censorship**.

In the ruling, the judge quoted from prior cases that:

> ***"'Securing First Amendment rights is in the public interest'" and "'the government does not have an interest' in the unconstitutional enforcement of a law."***[14]



Battling the Medical Mainstream

The **fish oil** controversy did not end with the **FDA**.

Defenders of conventional medicine like the **American Medical Association** and **American Heart Association** issued contradictory proclamations about fish oil's benefits or purported lack thereof.[15,16]

The back-and-forth was based largely on studies with huge **variations** in **EPA/DHA** potencies and/or unrealistic expectations of fish oil monotherapy.

Studies using ***higher*** omega-3 doses generally demonstrated fish oil's efficacy, whereas ***lower***-dose studies were often disappointing and resulted in mainstream medicine questioning fish oil's value.

The media parroted conventional medicine's vacillating positions, running tabloid-like headlines touting fish oil's cardio-protective benefits or attacking it as worthless, depending on the study released that day.

There *were* some contradictions, such as a study showing low-dose fish oil (**1,000 mg** a day of **EPA/DHA**) markedly reducing **fatal heart attack** risk while other studies showed little value using this **low** dose.[17,18]

Overlooked in much of this were **dietary patterns** in countries that had *higher* omega-3 intake in foods, and thereby needed *less* supplemental fish oil. These population groups might have benefited from a **low-dose** EPA/DHA supplement whereas dietary **omega-3** consumption in much of the **United States** is woefully **insufficient.**

The **American Heart Association** confused matters more in **2017** by recommending **fish oil** to **heart failure** patients, but not to the general population.[19] This ignores the importance of **heart attack prevention**.

Life Extension® published a rebuttal in **February 2018** titled "**An Illogical Position of the American Medical Association**" to describe the absurdity of recommending people wait to develop **heart failure** before ensuring optimal **omega-3** intake.[20]

Is A Consensus Being Reached?

Results from recent, large studies continue to validate the need for ***higher***-dose **omega-3** intake.

As mentioned in the introduction of this article, and in the **November 2019** edition of ***Life Extension***® magazine, robust benefits were found when a high dose (**4,000 mg/day)** of an **EPA-only** fish oil drug (Vascepa®) was used. The study found a **25%** reduction across a broad spectrum of **cardiovascular** disorders.[2]

In this same issue, we described why **1,000 mg** a day of an **EPA/DHA** supplement (and only **2,000 IU/day** of **vitamin D**) failed in its primary endpoint, but did yield meaningful risk reduction in several subgroups including:[17,21]

- **25%** reduction in **cancer deaths** in the **vitamin D** group when the first two years of follow-up were excluded,
- **28%** reduction in **heart attack risk**, and **50%** reduction in fatal heart attack risk, in the **fish oil** group, and
- **22%** reduction in **angioplasty** procedures (opening a narrowed coronary blood vessel, often with a stent) in the **fish oil** group.

At the **American Heart Association** annual meeting in **November 2019**, a presentation on a study that administered about **3,300 mg** of an **EPA/DHA** fish oil drug called Lovaza® revealed striking improvements in **cognitive functions** in older individuals.[22]

What made this study so compelling is that **blood levels** of **EPA/DHA** were carefully **measured**. The **cognitive benefits** occurred in those with an **omega-3 index** over **4%**. Here is the conclusion from this presentation made at the **American Heart Association** meeting:[22]

> ***"High dose EPA and DHA prevented cognitive decline in cognitively healthy coronary artery disease subjects, with younger subjects, nondiabetic subjects, and those achieving an omega-3 fatty acid index ≥4% having greatest benefit. These findings are especially important for coronary artery disease patients as coronary artery disease is a risk factor for dementia."***

What I continue to observe in the published data is **consensus** that ***higher***-dose **omega-3** intake is what induces meaningful risk-reduction benefits.

Overlooked Role of Dietary Omega-3s

No one argues with the idea that eating two to three **cold-water fish meals** a week reduces cardiovascular and other disease risks. This is nearly universally agreed upon and accepted, including in the medical profession and among researchers.

Yet missing from virtually all research on **fish oil supplements** is each study subject's **dietary intake** of **EPA/DHA**-rich **foods**.

To put this into perspective, a 4-ounce can of **wild salmon** contains about **2,000 mg** of total **omega-3s** providing about **1,800 mg** of **EPA/DHA**.

So, a clinical trial using only **1,000 mg** of supplemental **EPA/DHA** in people who regularly consume canned **wild salmon** might yield benefits because the total daily consumption of **EPA+DHA** is around **2,800 mg**.

On the flip side, individuals consuming typical Western **dietary patterns** that are nearly devoid of omega-3s may require far ***higher*** amounts of supplemental **EPA/DHA** (**3,300 mg** to **4,000 mg**) to achieve the same results.

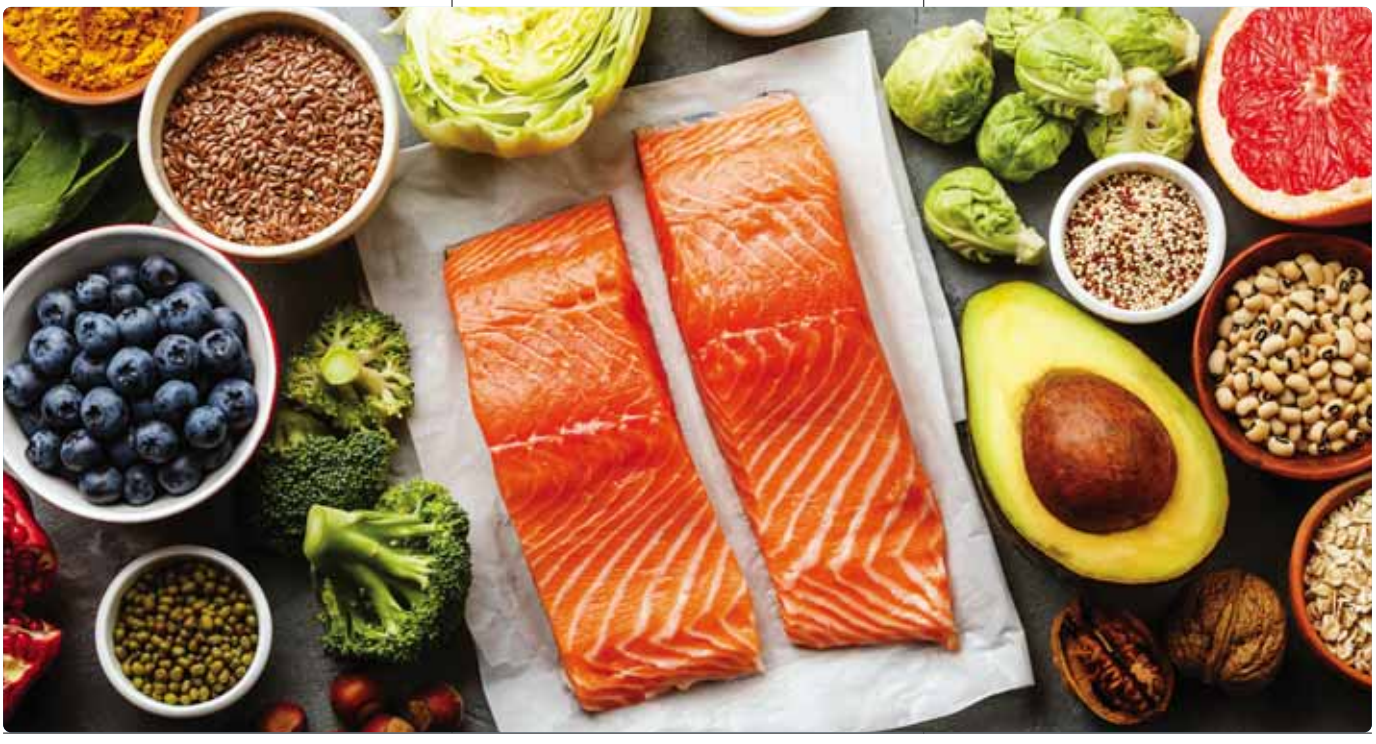
The significance of these differences cannot be overstated, both from a public health standpoint and on huge savings on fish oil drugs and supplements.

People whose diets *already* provide ample quantities of **EPA/DHA** will likely require lower potencies of fish oil drugs or supplements.

Yet a **one-size-fits-all** approach is the current protocol. The FDA now allows certain high-risk patients to be prescribed a **4,000 mg/**day potency of an expensive EPA-only **drug**—but advises against the same potencies of lower-cost **fish oil supplements**!

How This Impacts You

The importance of achieving optimal **EPA/DHA** status cannot be overstated. It impacts a person's risk of multitudes of disorders, many that are life threatening.



Your blood ratio of **omega-3 fats** to **omega-6 fats**—which can be measured with the **omega-3 index** blood test—is an important determinant of overall health status.

The good news is that pricing keeps dropping for the **omega-3 index** comprehensive fatty acid blood panel.

Results from this test can enable you to precisely determine how many **fish oil capsules** you need a day to achieve an optimal **omega-3 index**, which by most standards is over **8%**.

The recent study presented at the **American Heart Association** conference found meaningful **cognitive benefits** when omega-3-index scores were over **4%**.

I'll describe soon how you can obtain low-cost **omega-3/omega-6** blood tests that might enable you to reduce the number of fish oil capsules you take a day, saving you money over the long term.

Life Extension's Position on Fish Oil Dosing

For many decades, we've suggested most of our readers supplement with about **2,400 mg** of **EPA + DHA** each day from highly purified **fish oil**.

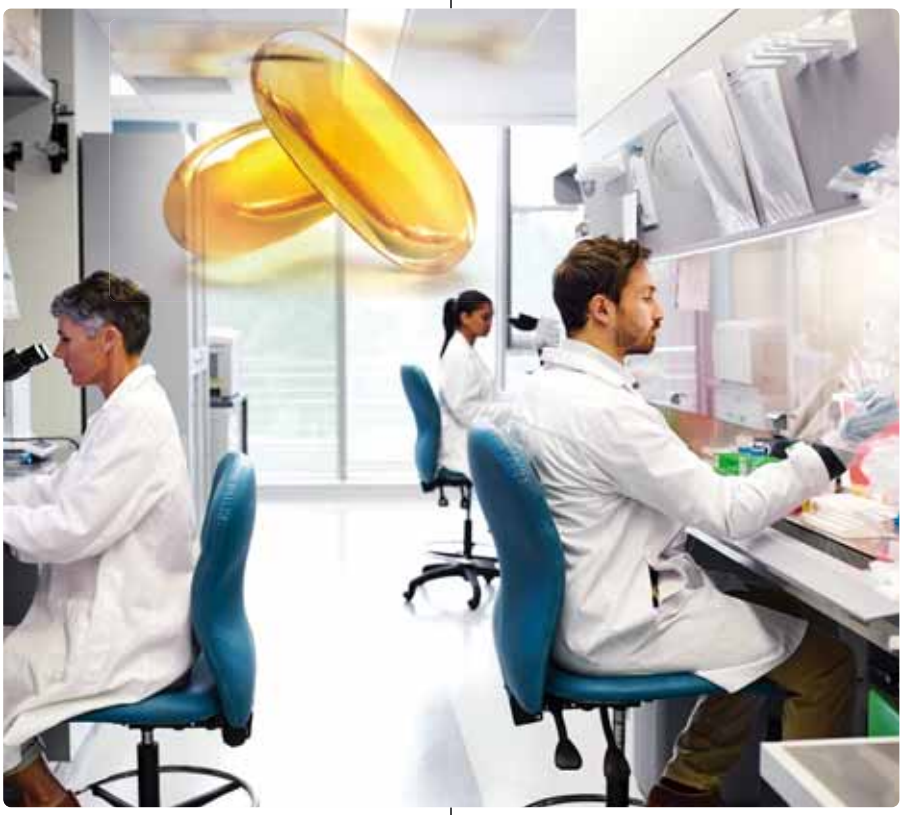
We know most of you consume **omega-3s** in your **diet** by eating cold-water **fish** meals and/or via **plant** sources like walnuts, flax, and other foods.

So, our typical reader may, on average, obtain over **3,000 mg-4,000 mg** each day of **EPA/DHA** from their **fish oil** supplement plus omega-3-rich dietary components.

We caution, however, that not all people, and perhaps very few, convert plant-based omega-3s to EPA/DHA. This is what makes **fish oil** so important but presents a dilemma for vegans.

People with stubbornly high **triglyceride** levels are advised to increase their fish oil intake to target a triglyceride **blood level** below **100 mg/dL**.

Based on published studies showing benefits with ***higher*** intake of **EPA/DHA**, more doctors are prescribing expensive **fish oil drugs**, often without considering an individual patient's **dietary** intake of the omega-3s.



Common-Sense Approaches

Supplementation with quality **fish oil** can cost about **$300** a year whereas fish oil **drugs** can cost over **$3,600** a year.

The **Omega-3 Index Complete** blood test includes the following measures:

- Omega-3 Index Percent (it should ideally be over **8%**)
- Trans Fat Index
- Omega-6:Omega-3 ratio
- Arachidonic acid:EPA ratio
- Full fatty acid profile

Results from this blood test provide a guideline for dietary changes and fish oil supplementation for each person's individual biochemistry.

Those who obtain few dietary omega-3s in their diet may want to boost their supplemental fish oil intake over **3,000 mg** a day, whereas those who eat **lots** of cold-water fish may reduce their supplemental dose below **2,400 mg** a day.

While these common-sense approaches are obvious to me and **Life Extension's** scientific staff, many hurried physicians are likely to stick with the labeled high doses of FDA-approved fish oil drugs, i.e. the *one-size-fits-all* approach.

Special Pricing: Omega-3 Index Complete Blood Test

We've recommended **omega-3 blood** tests for many years, but perhaps have not emphasized its importance enough.

With new studies validating the benefits of ***higher***-dose fish oil, there is an even greater value to optimizing one's fatty acid (**omega-3** and **omega-6**) blood status.

For a limited time, we are offering the comprehensive **Omega-3 Index Complete** test at the special low price of **$69**.

This pricing represents an exceptional value for all the important measurements you obtain.

We've extended our annual **Lab Test Super Sale** so this discounted price on the **Omega-3 Index** is valid for the next several months.

In This Month's Issue…

Most people don't know that after one suffers a **heart attack**, their risk of **stroke** is exponentially *higher*. A drug used to treat gout (colchicine) demonstrated a **74%** reduction in post-heart-attack **stroke risk**.

Learn what to ask your cardiologist regarding **colchicine** on page 73 of this month's issue.

The buildup of **senescent cells** continues to be recognized as a causative factor in degenerative **aging**. As you'll read on page 26 a plant flavonoid (apigenin) can reduce the **toxic secretions** that emanate from senescent cells.

Sulforaphane from broccoli has demonstrated powerful **anti-cancer** properties. Page 54 describes the best ways of transporting sulforaphane from the digestive tract into the blood.

Too Many Needless Heart Attacks

Growing consensus about **fish oil**, along with the new claims allowed by the FDA, will help enable more Americans to benefit from *higher* consumption of omega-3 fatty acids.

The tragedy is that it took so long for the benefits of omega-3s to be widely recognized.

Cardiovascular disease remains the leading cause of disability and death in the United States, especially in elderly population groups.

Armed raids by the **FDA** against those who recognized fish oil's benefits in the **1980s** resulted in countless numbers of cardiovascular events and astronomical medical costs for bypass procedures, stents and prescription drugs.

We look forward to science prevailing over the kinds of actions one might expect in an authoritarian, police state.

This happened when doctors in **Wuhan, China** warned of a **pneumonia** epidemic in **December 2019**, but were silenced with threats of arrests for "spreading false rumors."

This governmental **censorship** led to the deaths of hundreds of thousands of people worldwide from **COVID-19** disease.

FDA **censorship** of **fish oil** dating back to the **1980s** may have led to similar tragedies.

Turn the page for information on popular **Male** and **Female Blood Test Panels** and how you can obtain an **omega-3 index** at the lowest price ever.

For longer life,

William Faloon, Co-Founder
Life Extension Buyers Club

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