

FALSE PROFITS AND SILENT PARTNERS IN HEALTH CARE

BILL LANDS*

6100 Westchester Park Drive, College Park, MD, USA 20740

ABSTRACT

Traditional health care services have focused more on *treatment* of signs and symptoms of cardiovascular disease rather than on *prevention* of primary causal factors. This bias created a nation with increasing numbers of older people paying for increasing treatment costs. Treatment-oriented clinicians, drug companies and hospitals take a major proportion of ever-increasing health care dollars. Without prevention, American families gain little long-term relief from the highest health care treatment costs in the world. A lack of public accountability for valid surrogate endpoints continues to drain funds for treatments that do not remove underlying primary causes. It seems unethical and uneconomical to withhold community-wide primary prevention advice and only attend to people with clinical signs of disease. Also, treatments that remove a sign or symptom without removing the primary cause unethically set a sense of improved health while leaving unchanged the cause to continue harming future generations.

A good alternative would be long-term primary prevention that removes primary causal factors and prevents the onset of signs and symptoms of disease. Health insurance companies could be effective partners with corporate and individual subscribers by diverting resources toward preventing proved primary causes of disease. A chain of molecular events that causally connects modifiable food choices to many health disorders has a measurable mediator: the proportions of omega-3 and omega-6 in tissue highly unsaturated fatty acids (HUFA). Health risk assessment can monitor the diet-based proportions of tissue HUFA which influence hundreds of vital physiologic events. Many financial losses will likely be decreased by primary prevention advice to choose foods that increase intakes of omega-3 fats, decrease intakes of omega-6 fats and include fewer calories per meal.

INTRODUCTION

The Centers for Disease Control and Prevention (1) describes a situation out of control. Cardiovascular disease (CVD) is regarded as due to preventable causes, but USA annual losses to it are near \$400 billion. Each year, 1.2 million Americans have a heart attack, and 1 in 3 adult Americans have

*email = wemlands@att.net; phone = 1-301-345-4061

some form of cardiovascular disease. Although CVD death rates have decreased since 1980, the incidence and prevalence of CVD remains constant or increasing.

Why do the nation's large financial losses continue? Where does the money go? In the USA, most funds follow profit-oriented plans of corporations rather than altruistic scientific advice. Some corporations profit from the situation in which the nation continues to lose from lost productivity, expensive treatments and early deaths. By not preventing the primary causes of preventable disease, the nation can only look to continued social and financial losses. Who will prevent the primary causes of loss?

FALSE PROFITS

Whenever subscribers who pay annual life insurance premiums live longer lives, money is 'left on the table' as profit for life insurance companies. In contrast, a longer life in the USA includes many treatment expenses for preventable disorders that drain health care resources. Traditional health care services have steadily focused on *treating* cardiovascular disease without actually *preventing* the primary causal factors. This focus creates a nation with increasing numbers of older people paying for expensive treatment costs and future generations facing the same fate.

Long-term estimates of health care cost (2) make it obvious that expensive short-term treatments have left primary causes of disease unchanged with rising costs for subsequent generations. In this situation, treatment-oriented clinicians, drug companies and hospitals profit with an ever-increasing need for health care dollars. Individual Americans gain little long-term profit from a system that gives them the highest health care costs in the world.

In a market society, marketing messages are the major mode of public education. Corporations that profit from treating disease use their cash flow to publicize their 'success' and to market aggressively their services and products. Treatments that achieve some cash flow are readily made visible by marketing, and even small health benefits may have an exaggerated public display. However, treatment 'success' often is publicised with little attention to preventable primary causal factors, allowing the pandemic of CVD to continue. As a result, profits from such treatments are 'false' profits for the public that eventually pays for all services.

To slow increasing health care costs, employers are asking for help in having wellness programs for their employees to become better health care consumers (3). Greater 'wellness' in the families of employees could lower long-term health care costs (and allow lower premium charges to subscribers). Diverse services have rapidly proliferated to arrange and manage new 'wellness' treatment programs. Professional associations for those programs include coalitions facilitating more profits for physicians (e.g., the American College of Preventive Medicine) or more profits for wellness project managers

(e.g., Wellness Council of America). These associations will likely seek a larger share of health care dollars for their professional interventions and their increased marketing messages.

At the present time, many 'plug and play' wellness programs are offered by members of WELCOA or groups like the Michigan Health Management Research Center (e.g., 4). Such programs focus on disease identified by health risk assessment (HRA) measurements. They then offer treatments (secondary prevention) that decrease or slow progression of the measured HRA values. However, it seems unethical and uneconomical to withhold community-wide primary prevention advice and only wait to treat people with clinical signs of disease (5). Also, treatments that remove a sign or symptom without removing the primary cause unethically set a sense of improved health while the cause of disease continues unchanged. A better alternative would be long-term primary prevention that removes primary causal factors and prevents early onset of signs and symptoms in subscribers and their family members. Successful primary prevention stops the need for treatment expenses, and 'wellness' purveyors of some interventions may face a conflict of interest.

It is unfortunate whenever HRA monitors only associated biomarkers and signs that are not proved causes of fatal disease (6). A current lack of open accountability for valid surrogate endpoints for prevention continues to drain health care funds for treatments that do not remove underlying primary causes. Public accountability for using valid surrogate endpoints in prevention interventions has not been adequately provided by either the biomedical community (6,7) or health insurance actuaries. The prophets of 'wellness' spend much time, energy and attention on inadequately based advice and on treatments that fail to remove primary causes of fatal events. HRA measures of body mass index, blood glucose and LDL-cholesterol are surrogate signs that a primary cause needs to be prevented (7). However, decreasing a surrogate sign that is not a valid causal mediator will not likely decrease the disease.

All major risk factors associate with the occurrence of disease even when they are not the cause of disease. Association is not proof of cause. Sadly, market forces have diverted attention to inadequate inferences about blood cholesterol levels which were aggressively promoted without having a proved causal role in death (7,8). Intensive aggressive marketing supported by corporate profits incorrectly informs health professionals and the public that lowering blood cholesterol will remove a cause of disease and death (7,9). Important scientific evidence of limited health benefit and rigorous logic about primary causes of CVD disease and death are seldom present in the public marketing messages financed with treatment profits.

A summary of clinical trials with over 275,000 people (Table 1) showed that some treatments were little better than no treatment at all (10). Clinical trials showed that 'diet advice' from physicians was no better than no advice. Ironically, success from supplementing diets with omega-3 fats was not

TABLE 1

Efficacy of Clinical Interventions
 A meta-analysis of 97 randomized controlled trials with 137,140 people in intervention & 138,976 in control groups was reported by Studer M, *et al.* (10).

Risk Ratios for Overall Mortality

1.00 for fibrates (no better than control)
 0.97 for "diet advice"
 0.96 for niacin
 0.87 for statins
 0.84 for resins
 0.77 for n-3 fatty acids (less risk than control)

regarded as useful diet advice, but was considered a therapeutic treatment. Such 'silo mentality' favoring drug treatment thwarts recognizing how food choices are a preventable cause of harmful consequences. Ironically, despite knowledge of fish oil's benefit, family physicians with favorable attitudes toward nutritional therapy seldom recommend fish oils for their CVD patients (11).

Many clinical trials are carefully designed and financed by corporations to promote their further marketing efforts. However, published evidence often supports logical deductions beyond those initially intended. Evidence from the ENHANCE trial prompted open questions about whether 'cholesterol drugs' actually do any good (9, 12, 13, 14). Is elevated LDL-cholesterol the cause of death or merely a marker caused by the factors that actually cause CVD? HRA markers like BMI, waist/height ratios and body mass are secondary to transient postprandial rises in blood free fatty acid levels that cause vascular insults leading to CVD (while also causing insulin resistance and elevated glucose). The ACCORD, ADVANCE and VA-Diabetes trials (15) lowered elevated blood glucose but failed to lower CVD death. Also, the JUPITER trial showed that statin treatment can lower elevated levels of C-reactive protein (CRP), an acute stress protein associated with inflammatory conditions (16). However, the trial results open more public questions about whether LDL-cholesterol or inflammation mediates CVD deaths (13). Expenditures to lower non-causal biomarkers fail to prevent the primary cause of fatal disease and thus provide little public profit.

Despite widespread use of aspirin in secondary prevention treatments, doctors fail to inform the public that aspirin blocks excessive food-based omega-6 actions. While billions of dollars are spent annually for pharmaceuticals that moderate excessive omega-6 actions, the public remains uninformed of the modifiable dietary origins of omega-6 mediators that can be moderated by omega-3 actions. The molecular chain of events by which dietary n-6 fats cause inflammation, thrombosis, arrhythmia and death is well documented (7) but poorly communicated to the public. An easily prevented

imbalance in food choices underlies increased diet-based omega-6 mediators in tissues and increased severity of atherosclerosis, heart attacks, psychiatric disorders, workplace productivity losses, immune-inflammatory disorders, cancer progression and the length of stay in hospitals.

Poor public accountability for valid treatment surrogates is seen in the fact that not until 2008 did the USA mass media (9, 13, 14) openly raise skeptical questions about the unproved hypothesis that LDL-cholesterol levels cause cardiovascular disease and death. Public recognition that LDL cholesterol is not a valid surrogate indicator for prevention of CVD (7) has been delayed for decades by aggressive marketing of statin drugs using treatment profits. Health insurance actuaries should ask for evidence that the HRA measures used for treatment rationales are targeting proved causal mediators rather than associated signs that merely indicate some primary cause exists. Wellness programs that actually prevent primary causes will be the best way to decrease future expensive treatment services.

An altered flow of funds away from current treatment targets and toward valid primary prevention targets could be aided profitably by the actuaries for large health insurance providers (like Blue Cross, Medicare and Veterans Administration). They could join with biochemists to review and interpret evidence for valid connections between primary causes of disease and their consequences. Much biomedical evidence indicates likely success for simple food advice that increases intakes of omega-3 fats, decreases intakes of omega-6 fats and uses fewer calories per meal (7). More dialog between actuaries and biochemists is needed to sharpen the focus on connecting cause to consequence and on identifying causal mechanisms that can be prevented to cut the costs for treatments.

SILENT PARTNERS

Health insurers could profit with the public when the families of subscribers have their health maintained and disease is prevented. However, insurers currently are all too silent in this partnership. Hopefully, they will use their funds to identify effective wellness programs with low-cost monitoring of valid surrogate endpoints among individual subscribers. Such monitoring motivates people to comply with personalized diet advice that prevents primary causes and decreases the need for treatments. Subscribers and company actuaries both have reasons to urge wellness counselors to focus more effectively on preventing primary causes.

Wellness organizations currently paid by insurers to offer treatment (secondary prevention) services for people with identified disease may continue making easy profits. However, few of those organizations will profit from a reduced need for their services, and some market force must convince them to implement true long-term primary prevention. Actuaries in large health insurance companies will have accumulated records of lowered

use of expensive treatment services that openly identify the most effective ‘wellness’ services independent of marketing messages. When a health insurance actuary calculates that a certain wellness program with a long-term primary prevention perspective leaves more subscribers’ health care money ‘on the table’, the insurance company and its corporate subscribers will likely press for selecting and implementing that wellness program. In this way, large health insurance companies could become true partners with the public in preventing disease.

Blue Cross-affiliated companies may develop their own preventive wellness initiatives or use their collected premiums to outsource the initiative to subcontractors. Examples of such currently silent partners include Health Care Services Corporation (a Chicago-based set of four regional companies with 12.3 million members – including the 3.8million member BCBS of Texas); Highmark (a Pittsburgh-based company with 4.6 million members); CareFirst (a Washington, DC-based non-profit group with 3.1 million members); and BCBSKC (a Kansas City, MO company with 0.8 million members).

The cost of health-related losses in workplace productivity may be more than four times greater than medical and pharmacy costs (17). As a result, large self-insured corporations in the USA have reason to partner with the public to lower health-related losses and negotiate discounted health insurance premiums. In this context, collective bargaining negotiators might be the strongest advocates for employee preventive care (rather than an insurer who simply offsets higher treatment costs with higher collected premiums). Whenever a significant part of health insurance premiums are paid by the employer organization, that organization has incentive to support preventive programs that cut losses in workplace productivity and losses from treatment services by employees and their families. The public needs partners in prevention who are no longer silent about preventing proved primary causes.

PROFITING FROM HEALTH

A fascinating feature of food choices worldwide is the way that diverse populations unknowingly practice primary prevention. Simple blood analyses easily show the degree to which an individual has a modifiable diet-based tissue imbalance that causes much chronic disease (Figure 1; 18). Increasing daily foods with omega-3 fats will raise the proportions of omega-3 in tissue HUFA in a predictable way (19). Simultaneously lowering daily intakes of competing omega-6 fats allows each gram of omega-3 fat eaten to be more effective in lowering the proportion of omega-6 in tissue HUFA. People with less than half of their tissue HUFA as omega-6 have less omega-6-mediated tissue responses associated with less severity of atherosclerosis, heart attacks, immune-inflammatory disorders, psychiatric disorders, cancer progression

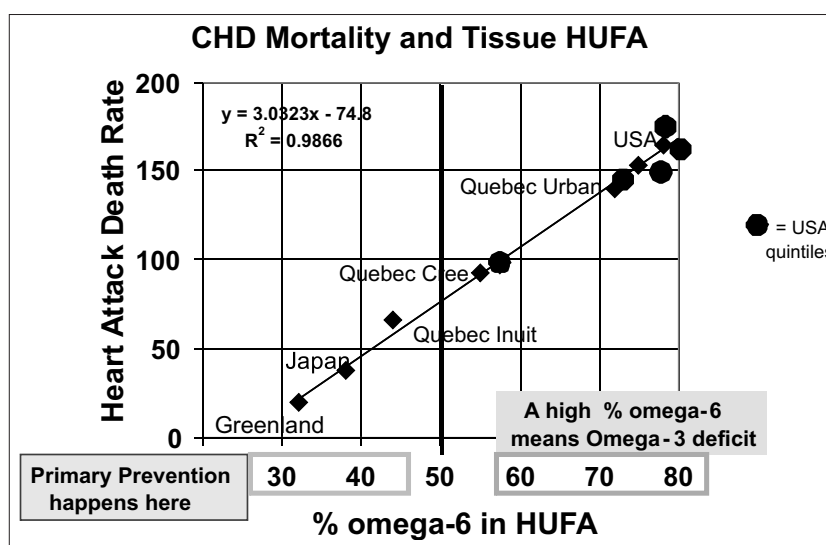


Figure 1

and length of stay in hospitals. A lowered proportion of omega-6 in tissue HUFA is a valid surrogate endpoint to monitor success when preventing cardiovascular disease and coronary heart disease (7). It is also a biomarker for attributable risk in all-cause mortality, stroke, homicide, bipolar disorder plus postpartum and major depression (20) as well as developmental disorders such as prosocial behavior, verbal intelligence quotient, fine motor control and communication and social development (21).

The Omega-3 Fatty Acid Subcommittee of the Committee on Research on Psychiatric Treatments of the American Psychiatric Association reported a meta-analysis of randomized controlled trials showing benefits of n-3 HUFA intake in moderating unipolar and bipolar depression (22). As a result, the Subcommittee recommends that all adults should eat fish two times per week, and patients with mood, impulse-control or psychotic disorders should consume 1 g EPA+DHA per day. An important estimate in this regard is that overall financial losses due to depression among employees can be ten-fold greater than medical and pharmacy costs (17). Employers of individuals who are lowering their omega-3 deficit to prevent CVD events may see decreased financial losses due to absenteeism and presenteeism (17). Primary prevention of an n-3 deficit in tissue HUFA seems likely to lower financial losses from atherosclerosis, heart attacks, psychiatric disorders, unproductive workplace behaviors, immune-inflammatory disorders, cancer progression and length of stay in hospitals.

The many actuaries employed by insurance companies (60% of the actuary profession) carefully examine the likelihood of insurance funds flowing to diverse subcontractors. Corporate executives and actuaries of health

insurance companies have a fiduciary duty to maximize shareholder's profits by decreasing excessive treatment costs. Optimal success requires wellness counselors to attend carefully to specific causal connections between lifestyle choices and debilitating disease. Sound inferences from detailed molecular evidence (7) will ensure designing preventive programs that effectively decrease need for treatment expenses. Like misleading warnings about blood cholesterol (7), misleading warnings about mercury in seafood (21, 23) have mistakenly diverted attention from implementing effective prevention of the marked omega-3 deficit in Americans that causes so much disease and requires so many diverse treatments in the absence of prevention. Corrections of the misleading fragmented advice may occur now that the FDA has begun open critical public comments to resolve current advice with information posted on its website at <http://www.fda.gov/OHRMS/DOCKETS/98fr/FDA-2009-N-0018-n.pdf>.

HOW TO SUCCEED

There is much power in monitoring a valid surrogate biomarker for a deficit or disease (6). Test results alert individuals to a personal problem and motivate each individual to comply with intervention advice. Tests also monitor successful compliance with intervention tactics. Although many insurers see value in health risk assessments, the much-used measures of body mass index, blood cholesterol, or blood glucose are not major causal mediators of CVD deaths. As a result, those measures are blunt tools compared to the proportions of omega-3 and omega-6 in blood HUFA that influence hundreds of vital physiologic events (7). Wellness counselors can use finger-tip blood assays of HUFA proportions (7) to motivate and monitor individuals' compliance (24) with focused diet advice developed easily with personalized interactive software like KIM-2 (7; 21). Knowledge of such tools needs to be in the hands (and minds) of health insurance company actuaries so that they can identify wellness subcontractors that will implement primary prevention procedures needed by subscribers and their family members.

After an individual has a brief introductory interaction with a diet counselor using simple planning software like KIM-2 (7, 25), subsequent 15-20-minute interactions coupled with a low-cost finger-tip blood assay of HUFA proportions will give robust evidence for improved levels of the valid surrogate endpoint (7). That, in turn, reinforces continued compliance and progress toward primary prevention. Bringing specific food choices into focus as a credible underlying cause of many serious diseases allows the intervention to spread to family members as primary prevention in the form of balanced food choices. The cost for semi-annual blood tests to motivate strong compliance with personalized diet advice and to reinforce making balanced food choices will likely be much less than the long-term costs of treatments needed in the absence of omega-6 education.

Imbalanced dietary intakes of relatively low omega-3 and high omega-6 fats are associated with major chronic health disorders worldwide (20) which collectively cause in the USA annual losses of over a trillion dollars. Estimate of a 'recommended dietary allowance' (26) for dietary omega-3 HUFA preventing a relative omega-3 HUFA deficit in tissues for 97–98% of the population is near 1-3 grams per day (20). This amount is small relative to the current USA average intake of 15-20 grams per day of omega-6 fats and 50-80 grams per day of total fat. In a subtle understatement, Hibbeln's report (20) concluded that the estimated USA need for dietary omega-3 HUFA "can likely be reduced to one-tenth of that amount by consuming fewer omega-6 fats." This insight into the competitive interactions of essential dietary fats leads to clearly-worded advice on food choices (e.g., 27) that will allow significant revision of narrowly based cost-benefit estimates (28). Actuaries have tools to show that lowering linoleate intakes helps omega-3 supplements save even more health care money.

An analysis of benefits from raising intakes of omega-3 fats and lowering intakes of omega-6 fats is in section 3 of a recent review (7). The evidence assembled also notes health benefit from eating fewer calories per meal to prevent excessive omega-6 in tissue HUFA from amplifying food energy-induced transient postprandial oxidant stresses that underlie atherogenesis (5). The RDA estimates of Hibbeln et al (20) used data that can also estimate a 'tolerable upper limit' (26) of omega-6 linoleate intake near 2-4 grams per day. That intake could allow the current average intakes of other essential fatty acids to give tissue HUFA proportions that would cut many diverse health problems for much of the population. A sharper focus on valid causal factors will let wellness programs predict more long-term profit for the public and its partners in prevention. We have the tools and information (7) to help wellness counselors develop a precise and productive focus that profits the public by shifting attention from treatment toward prevention. Health insurance actuaries have been silent for far too long about the neglect of effective prevention of the primary dietary imbalance that continues to drive massive national losses from preventable disorders.

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