

The nonsense of food labeling

By DR. JOHN BRIFFA

I've always thought that the health claims made by food manufacturers are largely meaningless.

For example, a food product can be advertised as "low in saturated fat" or "cholesterol free," but there is no good evidence that eating less of these particular foodstuffs has broad benefits for health. The "benefits" of eating a food low in saturated fat and cholesterol are, I think, perceptual more than based on any form of fact.

Also, even if dietary saturated fat and cholesterol had been proven to be detrimental to health, it does not necessarily make a food with low levels of these substances in it automatically healthy. For example, cow dung could be labeled "low in saturated fat" and "cholesterol free," but that does not make it good to eat.

The Daily Telegraph reported in April on the proposed European legislation regarding the labeling of food [1]. The story informs us that the U.K. consumer watchdog Which? warns that if proposed labeling laws are taken up, more than 90 percent of food products would be able to make some nutrition claim or other. Essentially, according to Which?, the thresholds under which claims can be made about things such as fat and sugar content are just set too high. We are facing a situation where we could see doughnuts and burgers being advertised and marketed as "low fat."

This news report contains a quote from a spokesman for the U.K.'s Food Standards Agency (FSA) telling us, "The FSA's view is that we must ensure that health claims do not mislead consumers. Draft proposals are being discussed by all member states at an EC level, and we are



LOW FAT: Could we see doughnuts with this label? PHOTOS.COM

pushing actively for legislation which puts consumers' interests first."

I was a bit surprised by this because the FSA's track record does not suggest this organization always puts consumers' interests first. I believe the agency continues to mislead the public about what is good and not so good to eat.

It warns, for instance, about the perils of saturated fat despite no good evidence this is the demon it's made out to be. And it continues to try to convince us of the "value" of starchy carbohydrates despite the fact that many of these tend to disrupt blood sugar and insulin levels in a way that predisposes to conditions such as weight gain, cardiovascular disease, and type 2 diabetes.

I noticed the other day that Sam Montel, resident nutritionist on the FSA Web site, writes, in response to a question on raisins: "Other healthy snacks include ... currant buns without icing, scones, or tea cakes."

Behind this, there is some evidence of the FSA having a closer than healthy relationship with the food industry, for example, the clear conflicts of interests those members of the former FSA Advisory Committee on Research had. This committee, whose role is to advise the FSA on matters of science and research, included a full-time employee of the food company Unilever. The chair of the committee also received funding from Unilever. As an addendum to this, I suppose it's worth pointing out that Dame Deirdre Hutton, chair of the FSA, owns shares in Unilever [2].

Such conflicts of interest would not be so troublesome if the FSA appeared to be giving us honest, impartial, evidence-based advice about what we should eat. But, in my view, they have failed miserably here.

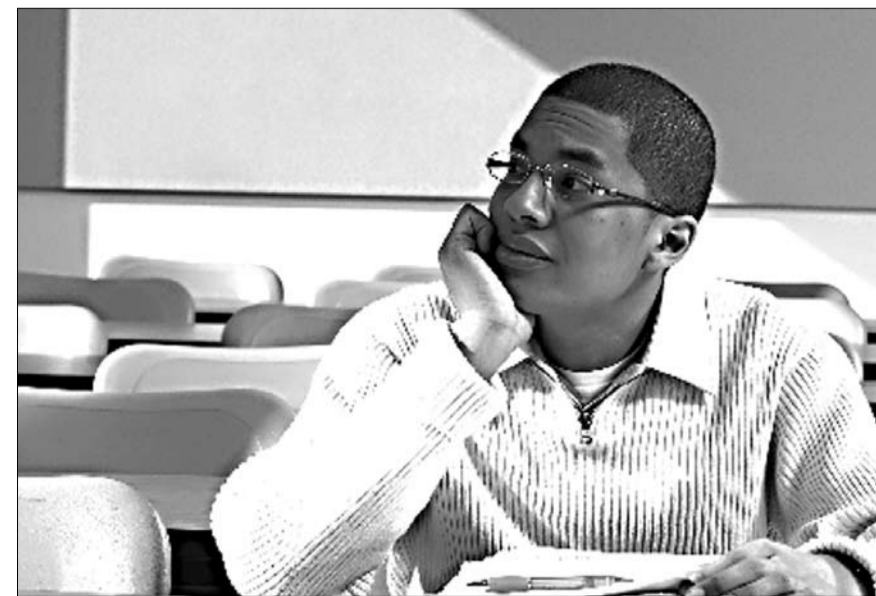
The FSA, as some of you know, also has some history of its own in the food-labeling arena. A while back, it introduced its "traffic light" labeling scheme, which rated foods as green, amber, or red on account of their sugar, salt, saturated fat, and overall fat content. The FSA's traffic light scheme enables oven chips to get four green lights, and therefore an implied stamp of approval, from the [U.K.] government, as something good to eat. The FSA is right to be wary of the proposed European food labeling laws, but I reckon it needs to sharpen up its own act in that area too.

References:

1. "Doughnuts 'could soon be advertised as low fat'"; telegraph.co.uk/news/5208893/Doughnuts-could-soon-be-advertised-as-low-fat.html

2. Food Standards Agency: food.gov.uk/about-us/lourboard/boardmem/damedeirdrehutton/

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DAYDREAMING: A good way of getting inspiration PHOTOS.COM

Daydreaming

Brain's problem-solving activated during daydreaming

(VOA News)—Have you ever tried to solve a problem but couldn't find the answer? Then, once you stop trying and move on to something else, the answer comes with ease.

Now a psychology professor examines how these moments of insight occur while we're daydreaming. Psychologist Kalina Christoff from the University of British Columbia notes that many times, as you're falling asleep or staring off into space, you come up with the answer to a problem that's been vexing you. It's that phenomenon that interests her, but she says it's hard to study something that happens so spontaneously.

So, Christoff had to devise a way of getting people not to pay attention. To do that, she asked study subjects to perform the routine task of touching a computer screen every time they saw a number appear. Then she would stop subjects about once a minute—so much that they would be distracted enough for collecting observations of when their minds were wandering.

"So what that allowed us to do is compare directly mind wandering versus thinking about the task and see what happens in the brain when you mind-wander," Christoff says.

As they were being tested, Christoff's subjects were lying inside of a brain scanner. The machine is able to see what parts of the brain become more active as a person con-

centrates or moves.

Christoff says she saw several things happening as people's minds started to wander from the repetitive task. First, the "default network" became active. Those are the parts of the brain that get busy as we do simple tasks, like watching TV or stirring a cooking pot. Christoff says she expected to see these parts of the brain engaged. But she also saw other parts of the brain in action.

"We also saw the 'executive network,' the part of the brain that helps you solve very difficult problems and helps you make executive decisions, also activated when people [were] mind-wandering," Christoff says. "When people mind-wander, very far from the brain becoming blank, it in fact becomes really active, and an expansive number of regions become quite active when your mind is wandering."

According to Christoff, usually these two systems of the brain do not act at the same time. She says this tells her something about what's happening as we become preoccupied with a simple task.

"Even though you might not be working in a particularly focused way on any one problem, you do have at your disposal a number of different systems of the brain to work that problem," Christoff says. "You have an expanded range of resources available to deal with an issue that you might be mind-wandering about."

Christoff says she'd like to do further research on how people can harness the power of the wandering mind and use it as a tool to help solve difficult problems.

Her research is published in the Proceedings of the National Academy of Sciences.

The 'ain't so's' about cholesterol

By W. GIFFORD-JONES, M.D.

Why are people so misinformed about cholesterol when so much has been published about it? After all, cholesterol has become a household name. It's hard to go to a social gathering without someone mentioning this fatty substance and his own cholesterol level. But as one wise sage remarked, "It's not the things you don't know that get you into trouble. It's the things you know for sure that ain't so." So, what ain't so about cholesterol?

It ain't so, for instance, that the only cause of coronary artery disease is cholesterol. Life is not that simple, and it's totally unrealistic to believe that one risk factor sends so many people to the great beyond. Rather, Matthew's Law is the culprit. It states that "It's the sum total of several factors such as obesity, diabetes, hypertension, lack of exercise, smoking, advancing age, and inadequate fiber in the diet that ends so many lives."

It ain't so that cholesterol is the devil it's made out to be. How many know that cholesterol is a necessary part of every cell in the body? Cholesterol is required for the absorption of fats and digestive juices, and there would be no loving without cholesterol, as it is needed to produce sex hormones! We would all die without cholesterol. And how many are aware that some studies show cholesterol-lowering drugs (CLDs) increase the risk of violent death, suicide, short-term memory loss, and some cancers.

It ain't so that cholesterol numbers determine whether or not you will have a heart attack. Cholesterol levels of men living in Edinburgh, Scotland, and Stockholm, Sweden, are identical. But the coronary death rate is three times greater in Scots. Maybe they don't eat as many veggies. Or they drink too much of their own Scotch!

Similarly, ethnic Japanese living in Japan and California have comparable blood cholesterol levels, but those in California have more coronary disease. Is this because of a change in diet or stress on their highways? No one really knows the answers to these questions.

It ain't so that low levels of blood



PILLS: "We have a population ... that now believes that the road to health is paved with pills, pills, and more pills." PHOTOS.COM

cholesterol prevent atherosclerosis and heart attack. One of the world's most famous heart surgeons, a Texan, reported years ago that 30 percent of patients who had a coronary bypass operation had normal blood cholesterol levels.

It ain't so that the only way our bodies obtain cholesterol is by the food we eat. Most patients are amazed to hear the liver produces 80 to 90 percent of the cholesterol in our bodies. You can't change the spots on a leopard, and it's hard to change the genetically controlled metabolism of the liver. Dietary changes help, but it requires a drastic change in food consumption to significantly reduce blood cholesterol.

It ain't so that the more cholesterol we eat, the more cholesterol is in the blood. The liver's production

of cholesterol is controlled much like the thermostat controls the temperature of our homes. Studies show that the more cholesterol consumed, the less the liver produces. Conversely, if the diet is low in cholesterol, the reverse is true, and the liver manufactures more cholesterol.

Here's a big "ain't so." It's not simply medical science that convinces people to take cholesterol-lowering and other drugs. I often write this column on Lake Canandaigua in upstate New York, so I keep my eye on U.S. health matters. It was recently reported by Excellus Blue Cross Blue Shield that, in 2007, in upstate N.Y. alone, \$241,530,000 was spent on just one cholesterol drug: Lipitor!

Another \$103,580,000 was spent on Prevacid to ease stomach prob-

lems, and \$74,360,000 on Effexor for depression. The point is, "That's the money in them thar drugs." I find it hard to believe that in one small corner of the United States so many people are suffering from high cholesterol levels, stomach, and nervous problems.

We have more than a sick economy these days. We have a population that's been programmed to illness, a population that now believes that the road to health is paved with pills, pills, and more pills. And it means we have a terribly ill society that keeps pharmaceutical companies flourishing.

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Folic acid added to food cuts birth defects

LONDON (Reuters)—Fortifying flour and pasta products with folic acid appears to cut the number of babies born with congenital heart disease, the most common of all birth defects, Canadian researchers said on May 12.

While food fortification is not mandatory in Europe, a 1998 Canadian requirement has led to a 6 percent drop each year in the number of such defects in Quebec, they reported in the British Medical Journal.

"These findings support the hypothesis that folic acid has a preventive effect on heart defects," Louise Pilote of McGill University in Montreal and colleagues wrote.

"Public health measures to increase folic acid intake were followed by a decrease in the birth prevalence of severe congenital heart defects."

Folic acid helps the body make healthy new cells. It is important that women get enough of it before and during a pregnancy to prevent

major birth defects involving a baby's brain or spine.

Leafy green vegetables, fruits, dried beans, peas, and nuts contain folic acid. It can be added to grain products or taken as a dietary supplement.

Even with fortification, many women do not get enough folic acid. In their study, Pilote and colleagues identified all infants born in Quebec with severe congenital heart defects between 1990 and 2005.

Their analysis showed no change in how many babies were born with severe heart defects in the nine years before fortification. But there was a 6 percent decrease annually for each of the seven years after fortification began.

The dip may seem modest, but given the complex treatment for the often-fatal heart defects, even a small reduction can significantly reduce health care costs, the researchers said.

Fraudulent trials behind asthma drugs cited, part 1

Rushed-through drugs receiving second look

By MARTHA ROSENBERG

A Texas physician is charging that a major allergy and respiratory management company knowingly produced flawed clinical trials of FDA-approved drugs currently on the market.

Trials of Singular, Serevent, Foradil, Flovent, Xolair, Accolate, and Xopenex conducted at the Tucson, Ariz., facility of Vivra Asthma & Allergy were corrupted by protocol violations and outright falsifications, says Robert Davidson, M.D., a

former clinical research subinvestigator (SI) at the facility.

San Mateo, Calif.-based Vivra Asthma & Allergy was the nation's largest respiratory disease physician practices until a merger with Lakewood, Colo.-based Gambro in 1997 and with El Segundo, Calif.-based DaVita in 2005.

Davidson charges that during aggressive recruitment schemes in the late 1990s, patients with abnormal EKGs, multiple risk factors for coronary artery disease, arrhythmias, pulmonary embolisms, rheumatic fever histories, acute illnesses, and even pituitary tumors were enrolled with impunity in trials that earned investigators as much as \$10,000 per patient.

Patients were "prescreened" for asthma drug trials with medically

unnecessary pulmonary function tests (PFTs) without their knowledge or consent and had medication dosages reduced in apparent efforts to qualify them for the lucrative trials.

Staff could be seen entering rooms where placebos and real drugs were mixed and unblinded, invalidating entire studies sent to the FDA as data for new drug applications.

The brazen "study buddy" and "crossover" arrangements, as staff referred to them, included churning or serially enrolling patients into clinical trials despite risks to their health and early terminations, coercing unwilling patients to participate, and directly falsifying patient study diaries, say documents filed by Davidson in a federal com-

plaint.

In 2006, the FDA mandated black box warnings on Serevent and Foradil, tested at Vivra and elsewhere, for increasing the risk of asthma-related death after adverse outcomes forced the early termination of a large clinical trial.

Warning labels for Singular, also tested at Vivra and under FDA investigation for suicidal side effects, were strengthened four times in 2007, and Raxar, an antibiotic tested at Vivra, was withdrawn in 1999 after being linked to 13 deaths.

FDA inspections of the Vivra Tucson facility, where Jay Grossman, M.D., served as principal investigator (PI) from 1993 to 2000, confirm the clinical subterfuge.

"Three study coordinators stated that they saw diary card blank

prior to subject entering exam room with PI for visit 2," reads a report from a May 5 through June 28, 1999, inspection obtained under the Freedom of Information Act. "Five to ten minutes after, the diary had approximately two weeks of diary symptoms and peak flow entered."

"On multiple occasions, over the last 8 months, the PI strongly counseled the SI to NOT mention potential risks of study participation to potential study subjects, (such as arrhythmia, drug-drug interaction, and so on) so as to not 'scare them away,'" the report reads elsewhere.

"Coordinator stated that subject called to say she could not participate in a 12-hour-a-day study due to her schedule. PI called the subject's [sic] estranged husband to say

that they had to get the disease under control."

Nor was patient safety apparently protected.

"PI enrolled subject into study despite subject having a clear study exclusion (maintenance inhaled corticosteroid therapy)," a report states elsewhere. "Subject subsequently experienced a SAE [severe adverse event] (hospitalized) while in the study. Moreover, this subject had recently participated in a prior study [in] which she required multiple prednisone bursts and multiple courses of antibiotic therapy for several bouts of acute sinusitis with asthma exacerbation."

Part 2 of this article will appear next week.

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