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ACSH PROGRAMS AND

ACTIVITIES

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Drug Pipeline Gets Clamped by Jittery FDA

By Dr. Henry I. Miller and Jeff Stier, Esq.

This article appeared on October 9, 2006 in Investor's Business Daily:

At a time when the American population is aging and more seniors are suffering from chronic diseases, the pharmaceutical pipeline is drying up.

In spite of more powerful and precise technologies for drug discovery, purification and production, development costs in the past twenty years have soared, the length of clinical testing is increasing, fewer drugs are being approved, and applications to the FDA by the industry for marketing approval have been decreasing. All this bodes ill for patients.

Mismanagement and risk aversion at the FDA are largely responsible. Regulators keep raising the bar for approval, especially for innovative, high-tech products. The agency is requiring more patients in clinical trials, its demands for post-marketing clinical trials have proliferated wildly, and "risk management" plans for newly approved drugs have been excessive and punitive.

A new report on "drug safety" by the quasi-governmental Institute of Medicine (IOM) will remedy none of these shortcomings. In fact, many of the recommendations will make the FDA more risk averse, reduce the number of drugs emerging from the R&D pipeline, and compromise public health.

For example, the IOM report recommends that labels on newly approved drugs include a black triangle warning for the first two years on the market, and that direct-to-consumer advertising of new drugs be restricted. These are bad ideas.

Most side effects are identified in trials before drug approval. Adverse reactions are then weighed vs. the drug's potential benefits. But it's impossible to identify every possible side effect, even in large pre-approval trials. Only with careful post-marketing surveillance, in which a larger, more diverse group of patients is monitored, can the rarest reactions be detected. This approach tries to balance benefits of getting drugs to market in a timely fashion, with risks present in putting any drug on the market.

Also, we must consider the risk of not making a drug available to sick patients. Consider patients newly diagnosed with pancreatic cancer, Lou Gehrig's disease, or the hemolytic-uremic syndrome recently associated with E. coli-contaminated organic spinach. Regulators are seldom called to account for deaths of patients who don't get the new drugs they need in a timely way.

New drugs should not be unfairly stigmatized. They confer an advantage over older ones in reducing mortality. In a study of patients who took drugs from January to June 2000, those who took newer medications were less likely to die by the end of 2002.

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Blogspot: Will Analyzing Body Fluids Improve Health?

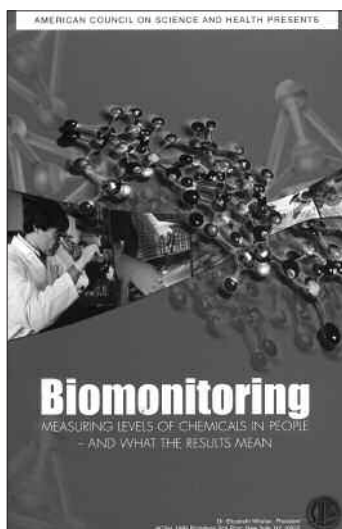
By Dr. Gilbert Ross

This October 3 item is just one recent article from ACSH's blog, *HealthFactsAndFears.com*.

Gov. Schwarzenegger has signed another law on the environmentalists' "must-have" list: this one establishes the state's new biomonitoring program, in which a number of volunteers representing a cross-section of Californians would consent to have their blood, urine, and other body tissues and fluids analyzed for an as-yet undetermined number of chemicals. The stated purpose would be to accumulate data in an attempt to link chemicals exposures to various adverse health outcomes. The plan is to perform these assays every two years and release the results publicly.

The "governator" vetoed a similar bill one year ago but claims this one has been significantly improved by the mandate to have the panel overseeing the program consist of experts with relevant epidemiological, statistical, and toxicological backgrounds.

In fact, it has been established that Americans do indeed have trace amounts of a wide variety of chemicals in our bodies: the CDC does its own federally backed biomonitoring program every two years. In their last report, they assayed 148 substances in a large sample from their own database of the National Health and Nutrition Survey, and the CDC found nothing alarming. Indeed, the scientists of the CDC reminded us that "merely because a substance is



found in our bodies, does not mean that it represents a threat to health." ACSH came to the same conclusion in our peer-reviewed publication *Biomonitoring: Measuring Levels of Chemicals in People - and What the Results Mean*.

So one might ask, aside from spending a great deal of time and money doing the

same type of study in California, what will the people of that state gain from the new initiative? Your guess is as good as mine – but the sentiment expressed by a co-author of the law, State Senate President Pro Tem Don Perata, may yield a clue. He is quoted as having a "personal interest" in enacting this into law because "I have in my office alone five women recovering from cancer, and I can't believe that my experience is much different from other people."

It seems that Sen. Perata has convinced the Governor that trace levels of chemicals might be responsible for the mini-epidemic of cancer in his office. This idea makes no scientific or epidemiologic sense – it is what we call an "anecdote," in which a person generalizes his own experience into a population-wide conclusion. One conclusion from his experience may be supportable: the higher rate of cancer survival we are now attaining with modern medical detection and treatments.

As for the implied link between chemicals and cancer: there is simply no evidence linking our exposure to environmental chemicals to any form of human cancer (see also: *Traces of Environmental Chemicals in the Human Body: Are They a Risk to Health?*). In fact, cancer rates of almost all types are stable or decreasing in the U.S., regardless of the introduction of many new chemicals to our environment over the past several decades.

It is unlikely that the state authorities in charge of California's biomonitoring program will be able to discuss its results in as expert a manner as CDC's science-based interpretations, and the new program will not include the risk-based framework that is needed to communicate the meaning of biomonitoring information. Instead, Californians may well be unnecessarily frightened by results of such biomonitoring, without reaping any public health benefit. Similar to its "pioneering" effort to reduce health risks by labeling virtually everything in the state a "possible carcinogen" via Prop. 65, California's latest effort will produce much sound and fury, pleasing its "green" proponents, but with no significance for the health of citizens. ♦

Gilbert Ross, M.D., is Executive and Medical Director of the American Council on Science and Health (ACSH.org, HealthFactsAndFears.com).

A Message from ACSH's President:

My Testimony on Trans Fats

By Dr. Elizabeth M. Whelan

The day before Halloween, I faced some frightening crowds at New York City Department of Health hearings. They were protesting in favor of banning trans fatty acids (TFAs). This is part of my testimony that day:

High levels of dietary trans fats, derived primarily from partially hydrogenated vegetable oils, can raise levels of LDL, the so-called "bad cholesterol." But TFAs are only one of several dietary factors that affect blood lipids, and, more importantly, serum cholesterol is only one of several factors that may influence the risk of heart disease. Cigarette smoking and high blood pressure, as well as diabetes and obesity, contribute far more to heart disease than any specific dietary factor.

Any practicing physician who has treated patients with elevated cholesterol levels will tell you that even the strictest low-fat diets often result only in modest cholesterol reduction. Given the scientific facts, why is there such an uproar — one with regulatory teeth — about TFAs?

First, in recent years, public health authorities have increasingly turned to regulation to combat chronic disease in fashion similar to using regulation in fighting chronic disease — such as requiring water chlorination and inoculations. The problem is that government intervention for chronic diseases, which are primarily linked to lifestyle factors, is intrusive and simply will not work.

Second, as the hyperbole about TFAs has escalated, physicians and scientists have largely remained mute on the topic. Silence is interpreted as agreement — and the momentum for bans builds.

Third, the food industry has turned the fear of TFAs into a brilliant marketing strategy — trumpeting the "No Trans Fats" claim on labels. Unsuspecting customers will conclude the products are healthier — and maybe even think they are lower in calories — when in fact there are no health benefits. All fats, saturated or not, contain nine calories per gram. There are no caloric savings from replacing TFAs with other fats. ◆

But trans fats have become the latest simple health scapegoat for our complex problems. ACSH will just have to keep weighing in to set the record straight, on this issue as on so many others.



ACSH Donor Profile:

Shep Barbash

By Molly Lee

ACSH Donor Shep Barbash describes himself as a "recovering journalist" who is now working in education reform. It was through his work as a journalist that he had the opportunity to meet and interview ACSH Trustee and Nobel Peace Prize winner Dr. Norman Borlaug. Borlaug's name and the names of other well-respected scientists on ACSH's list of advisors impressed Mr. Barbash enough to make him become a supporter of ACSH's work.

"ACSH does a terrific job of following science in a measured, cautious way," he says. After reading one of ACSH President Dr. Elizabeth Whelan's well-reasoned and science-based op-eds, Shep was convinced of the organization's "fearlessness." He also notes the importance of prioritizing what health risks to worry

about and sees ACSH as one of the few health organizations that puts risks in perspective.

Mr. Barbash was the Bureau Chief for the *Houston Chronicle* in 1988. He has also written a book on Mexican folk art with his wife, who is a photographer. Additionally, he works closely with Reading First, the federal reading program. He now works as a freelance writer and an education reform advisor in Atlanta.

"As a writer, I'm always looking for the best and most measured source of information," he says. "ACSH has become my first source of information for health and science issues."

ACSH is grateful to Mr. Barbash and our many donors throughout the country for their continued contributions. ◆

Molly Lee is the Earhart Foundation Research Associate at the American Council on Science and Health.

Major Publications from ACSH (October and November 2006)

Helping Smokers Quit: A Role for Smokeless Tobacco?

by Kathleen Meister, M.A.

According to the Centers for Disease Control and Prevention, about 45 million Americans continue to smoke, even after one of the most intense public health campaigns in history, now over 40 years old. Each year some 438,000 smokers die from smoking-related diseases, including lung and other cancers, cardiovascular disorders, and pulmonary diseases.

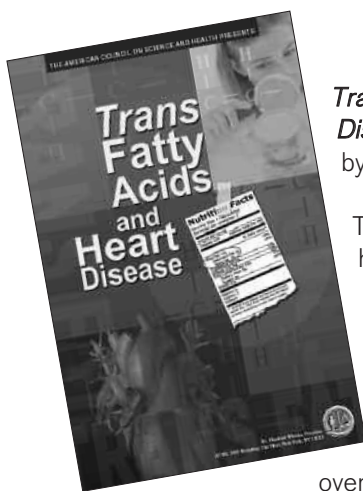
Many smokers are unable – or at least unwilling – to achieve cessation through complete nicotine and tobacco abstinence; they continue smoking despite the very real and obvious adverse health consequences. Conventional smoking cessation policies and programs generally present smokers with two unpleasant alternatives: quit or die.

A third alternative, tobacco harm reduction, involves the use of alternative sources of nicotine, including modern smokeless tobacco products. A substantial body of research, much of it produced over the past decade, establishes the scientific and medical foundation for tobacco harm reduction using smokeless tobacco products.

This report provides a description of traditional and

modern smokeless tobacco products. It reviews the epidemiologic evidence for low health risks associated with smokeless use, both in absolute terms and in comparison to the much higher risks of smoking. The report also describes evidence that smokeless tobacco has served as an effective substitute for cigarettes among Swedish men, who consequently have among the lowest smoking-related mortality rates in the developed world. The report documents the fact that extensive misinformation about smokeless tobacco products is widely available from ostensibly reputable sources, including governmental health agencies and major health organizations.

The American Council on Science and Health believes that strong support of tobacco harm reduction is fully consistent with its mission to promote sound science in regulation and in public policy, and to assist consumers in distinguishing real health threats from spurious health claims. As this report documents, there is a strong scientific and medical foundation for tobacco harm reduction, which shows great potential as a public health strategy to help millions of smokers.



Trans Fatty Acids and Heart Disease

by Kathleen Meister, M.A.

Trans fatty acids (TFAs) in food have been causing unnecessary panic in the media and among food activists in recent months. Overstating the health effects of TFAs is harmful to public health because it promotes an overemphasis on this single dietary factor as opposed to other aspects of diet, other

risk factors for coronary heart disease, and other public health priorities. By drawing attention away from other, more significant health risks, the current exaggerated focus on TFAs may actually cause more problems than it solves.

TFAs are one of several dietary factors that affect blood lipid levels, and blood lipid levels are one of several factors that influence the risk of heart disease.

Until the early 1990s, scientists generally believed that the impact of TFAs on blood lipid levels was minimal, and that fats that contain TFAs were a



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desirable replacement for saturated fats. More recent research indicates, however, that TFAs raise blood levels of undesirable low-density lipoprotein (LDL) cholesterol to an extent comparable to that produced by saturated fatty acids and that TFAs, particularly at high levels of intake, may also lower levels of desirable high-density lipoprotein (HDL) cholesterol, an effect that saturated fatty acids do not share.

Exaggerated estimates of the benefit that could be achieved by removing TFAs from the diet have occasionally appeared in the scientific literature and the news media, though. These estimates are based on epidemiological data that may not reflect a cause-and-effect relationship.

Contrary to some reports in the news media, the calorie counts of fats containing TFAs are no higher than those of other fats. The scientific rationale for limiting the consumption of TFAs is related to effects on blood cholesterol levels, not effects on obesity. All types of fat are equally high in calories.

As part of an overall effort to reduce risk factors for heart disease, advice to the public to limit consumption of both saturated fatty acids and TFAs by substituting polyunsaturated or monounsaturated fats whenever possible is justified by the scientific evidence. Scare tactics, including claims that there should be zero tolerance for TFAs in the food supply, are not justified. ♦

Long before Thomas Campbell Jackson, joined ACSH's Board of Trustees, he was a supporter of ACSH's sound science mission. Like many of ACSH's donors, Thomas knew that his donations to ACSH go a long way, so he wanted to give more.

Thomas found a way to do that, without it costing him more. In fact, he wound up *saving* money — money that he would have otherwise had to fork over to the government. Thomas joined the “**ACSH Investors**,” a group of people who, perhaps like you, prefers to **give more to ACSH and less to the government.**

A savvy investor, Thomas held stocks that grew in value and would have been subject to capital gains tax when sold. So instead of selling the stock, paying the taxes, and donating what was left, Thomas donated the stocks directly to ACSH, and not only did he legally avoid capital gains taxes, he was permitted to get a deduction for the amount the stocks were valued at when he donated them!

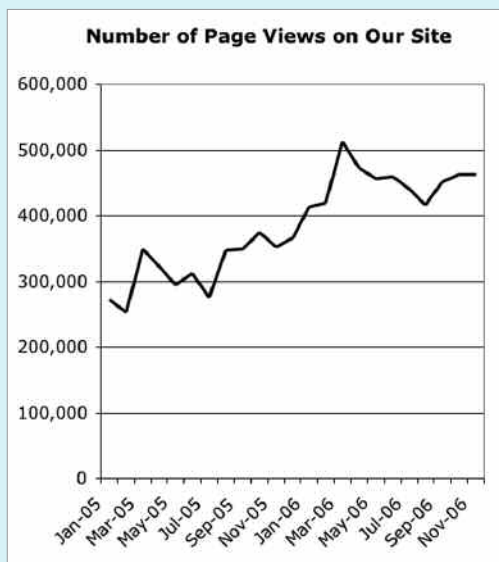
Did you know that most of ACSH's donated stocks, mutual funds, and other investments come in at the very end of December? Now would be a great time to join the club!

Join Thomas and the other **ACSH Investors** and donate appreciated assets to ACSH! Please call Jeff Stier at 212-362-7044 and he'll walk you through the quick and easy process. Call before the end of the year, and join other ACSH donors who are helping promote sound science while saving on their 2006 taxes! ♦



ACSH gets a four-star rating from Charity Navigator!

ACSH Sites Flourish



During the months of October and November:

- visits to ACSH.org averaged over 200,000 per month, vs. an average of 100,000 per month for 2005
- visitors to our site TheScoopOnSmoking.org averaged 29,000 per month vs. 12,000 per month in 2005
- reports were downloaded from ACSH.org over 10,000 times
- thirty new articles appeared on our blog HealthFactsAndFears
- nine columns and letters to the editor by ACSH staff appeared in various prominent publications

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Drug Pipeline Gets Clamped by Jittery FDA

The estimated mortality rates were directly related to time that had elapsed since approval of the drugs. For pre-1970 drugs, the estimated mortality rate was 4.4%, while the mortality rates for drugs approved during the 1970s, 1980s, and 1990s were 3.6%, 3%, and 2.5%, respectively. Not surprisingly, drugs are getting better all the time.

As to restricting direct-to-consumer advertising of newly approved drugs, studies show that such advertising encourages patients to visit their doctors and to discuss their medical problems; in this way, they obtain more timely diagnoses and treatment.

Another ill-advised IOM recommendation — a call for at least 60% of medical experts serving on FDA advisory panels to be free of “significant” financial involvement with pharmaceutical companies — would make it harder for the agency to obtain expert advice. The FDA needs more and better experts, not more restrictions on those most qualified to serve. Any actual evidence of bias, from financial or other causes, should be weeded out in committee review.

The exclusion from review panels of all scientists who have had relationships with industry would leave a substandard pool of possible advisers to opine on difficult scientific and medical questions.

Finally, the report recommends “additional financial and staff resources” for the agency. Nonsense. The FDA is fat, slow and inefficient. Instead of further fattening, it needs a diet. As economist Milton Friedman has observed, only in government do we respond to a failed enterprise by making it bigger.

How could the IOM committee have gone so wrong? Simple. The FDA, which commissioned the study, framed the IOM panel's mandate so narrowly — to encompass only “drug safety,” rather than overall benefit to patients from new drugs — that many of the specious conclusions were inevitable. That's like performing a study on the environmental benefits of ending all combustion of oil and natural gas, without considering the broader implications.

What the FDA needs is competent management, discipline in the ranks, more effective risk-benefit balancing, a commitment to permitting patients and physicians to assume more responsibility for the risk of medical interventions, and the banishment of politics from regulation. The IOM panel's recommendations won't get us there. ◆

Miller, a physician, is a fellow at the Hoover Institution and an ACSH Trustee. Stier, an attorney, is an associate director of the American Council on Science and Health.



Media Spotlight

The media often use editorials or letters written by ACSH experts or quote ACSH experts in articles. Examples from October and November 2007 include:

The Washington Times

THE WALL STREET JOURNAL

The New York Times

- “Sweetener Lowdown” (from **Dallas Morning News**) quoting ACSH’s Todd Seavey 10/2
- “Bad Drugs/Faux Pharmacies/Fear and Pharmaceuticals” (from **TCSDaily.com**, **LegalNews.TV**, and **Washington Times**) by ACSH’s Dr. Henry I. Miller 10/5
- “Drug Imports: A Prescription for Danger?” (from **LegalNews.TV**) by ACSH’s Jeff Stier 10/6
- “Drug Pipeline Gets Clamped by Jittery FDA” (from **Investor’s Business Daily**) by Stier and Miller 10/9
- “Vaccinating School Children Also Protects the Elderly” (from **Wall Street Journal**) by ACSH’s Dr. Gilbert Ross 10/12
- “ABC Slams Companies for Donating to Breast Cancer Research” (from **BusinessandMedia.org**) quoting ACSH’s Dr. Elizabeth Whelan 10/13
- “Editorial Roundup” note on population (from **Associated Press**) quoting Seavey 10/19
- “Chemicals and Pubescence” (from **New York Times**) by Ross 10/24
- “KFC Will Remove Trans Fats from Menu” (from **NewsChannel5.com** Nashville) quoting Stier 10/30
- “I’m Amazed by the Proposed Trans Fat Ban” (from **Houston Chronicle** – one of numerous venues to note ACSH’s trans fat position) quoting Whelan 10/30
- “Health Officials Target Hazards of Spit Tobacco” (from **Pittsburgh Post-Gazette**) citing ACSH 11/1
- “Trans Fat Free at Last” (from **Reason.com’s Hit & Run blog**) quoting ACSH’s report 11/1
- “Flu Fighter” (from **Fitness** magazine) quoting Ross 11/1
- “Food Fight: Big Apple to Take a Bite Out of Trans Fat...” (from **TheHeart.org**) citing ACSH 11/1
- “Morbidly Obtuse” (from **NationalReview.com**) by Whelan 11/2
- “Austin Shouldn’t Ban Trans Fats” (from **Daily Texan**) citing Whelan 11/7
- “Trans Fat Antidote” (from **Washington Times**) by Whelan 11/12
- “Trans-Fat Criminals” (from **CEIOpenMarket.com**) quoting Whelan 11/2
- “Trans Fat Threat Exaggerated by Some Doctors” (from **Courier-News** and other papers) by Whelan 11/12
- “Two Cheers for the FDA” (from **The American**) by Ross 11/20
- “Quotes on Turkey” (from **Weird News BNI**, **Washington Post**, etc.) quoting Whelan 11/21
- “ACSH Urges MDs to Help Patients Kick the Habit” (from **NicotineNews.blogspot.com**) quoting Ross 11/21
- “Public Misled” (from **Financial Post**) citing ACSH 11/22
- “Jay Lehr Responds to Eric Schlosser” (from **Heartland.org**) citing ACSH 11/22
- “An All-Natural Chemical Feast” (from **New York Post**) by Whelan 11/23
- “Chemicals and Kids’ Brains” (from **Boca Raton News**) by ACSH’s Molly Lee 11/24

ACSH Journal Publication:

- “Not the Next Tobacco: Defenses to Obesity Claims” by Joseph P. McMenamin and Andrea D. Tiglio in **Food and Drug Law Journal** 10/10

ACSH staff also make frequent appearances on TV and radio, and the past two months have seen Stier on **Regional News Network** stations 10/27 on smoking bans and on **CBS’s Early Show** 10/31 on trans fats, Ross on **Telemundo** 11/9 on a medicine recall and Atlanta’s **640 WGST Radio** 10/30 discussing bird flu as well as in an October public service

announcement about flu shots, Kava on **Washington Post Radio** 10/16 on soda and **CNBC** 11/21 countering CSPI’s Dr. Michael Jacobson, and Whelan on **ABC News** with Charlie Gibson – plus ACSH devising an environmental course curriculum with **Northwood University** and the citation of ACSH on a **NY1** trans fat debate 10/31. ♦

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