The Voice of the American Council on Science and Health

A Sampling of ACSH's Press and Internet Media Coverage January 2012 – June 2012

MEDIA UPDATE

MR. GORBACHEV- TEAR DOWN THIS LAB!

By Jonathan (Josh) Bloom, Ph.D.
June 29, 2012

Medical Progress Today

It never stops.

Anyone who keeps up with pharmaceutical industry news knows that it is impossible to go very long without seeing another round of job cuts. Sometimes, just to break up the monotony you even get to read about a plant closing.

The monotony was certainly broken on Tuesday, when Roche dropped a bomb on 1,000 employees, as well as the township of Nutley, N.J., which has been their R&D home since 1932.

The employees were summoned to the cafeteria and auditorium, where they were given boxed lunches along with the news that the campus would be shut down and they would lose their jobs. One can only imagine how bad this would have been without the lunches.

And, of course there was the usual corporate-speak statement was issued by the company: Roche is committed to handling the designated job reductions in a respectful manner and to finding socially responsible solutions for the employees affected. This includes informing employees who will be affected as soon as possible and providing appropriate plans and programs to support them during this transition process.

Translation: Expect to be eating a lot more boxed lunches.

So now Roche scientists will join the tens of thousands of us who have already dropped through the trap door, further illustrating how far the pharmaceutical industry has fallen--and also how fast. Only ten years ago, ten thousand people were employed at the Nutley site. Another pharmaceutical ghost town in the making.

> "The last thing we need is a big pile of bricks with air conditioning."

And this is not the only one. Not even close.

According to Ed Silverman, who has been writing the influential Pharmalot blog for over five years, in 2011 there were thirty eight plant closures. A horrifying number, yet in 2010 it was far worse--sixty five sites were shuttered.

This is hardly surprising, considering the mentality behind the "new paradigm" in drug discovery. GlaxoSmithKline's CEO Andrew Witty pretty much says it all--"We've got no interest in physical facilities. We've been reducing our own. The last thing we need is a big pile of bricks with air conditioning."

Good thing no scientist was holding one of those bricks when he made that statement.

So, what's it going to be, CEOs? Is it really a good idea to keep dismantling the drug industry, demolishing facilities and careers along the way?

One of the most widely-read pharmaceutical bloggers, Chemjobber, whose site is the place to go to look for employment, has his own thoughts on the matter:

"I hope the multiple sacrifices of productive research sites to the gods of quarterly profits are worth it, because we're putting a lot of good chemists and biologists out of work permanently. Where are future advances in pharmaceuticals going to come from? Neither Kalamazoo or Ann Arbor, Michigan, apparently. Nor New Haven, Connecticut. Nor Pearl River, New York or Sandwich in the UK. And now, not Nutley, New Jersey."

I couldn't have said it better myself.

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ACSH is a nonprofit, tax-exempt consumer education association directed and advised by over 350 prominent physicians, scientists and policy experts. It is dedicated to analyzing and reporting on issues pertaining to the relationships of food, chemicals, pharmaceuticals, lifestyles, the environment and human health.

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Dr. Ross To NY Senate: Don't Ban E-Cigarettes

June 20, 2012

Dear Senators:

Speaking for The American Council on Science and Health (ACSH, www.acsh.org), a consumer education and advocacy nonprofit devoted to sound public health policy based on science, we most strongly opposed any consideration of a ban on the sales/marketing of electronic cigarettes (e-cigarettes, or ENDS--electronic nicotine delivery systems) in the State of New York. This proposal, by Sen. Hannon (S07635), is not only NOT a benefit to public health, it is in fact directly counter to it.

On the other hand, ACSH fully supports Senator Johnson's bill, S02926B , which would bar sales of ENDS (e-cigarettes) to minors.

AMERICAN COUNCIL ON SCIENCE AND HEALTH

Smokers are generally strongly addicted to this lethal habit--not only to the nicotine, but to the whole behavioral pattern of smoking. Whereas the commonly-used, FDA-approved methods--patches, gums, medications--work only infrequently, e-cigarettes nearly replicate the behavior of smoking and supply nicotine as well. While the totality of the data are still being accumulated, clearly this technique has a high likelihood of truly helping addicted smokers quit, before it's too late. Concerns have been raised about "chemicals" and "carcinogens" in ENDS vapor, but the levels of these detected do not pose a health threat and are in fact lower than can be found in nicotine patches, etc.

And consider the alternative: e-cigs. are clearly far less toxic than cigarettes. Smoking cigarettes for 2 months is more harmful than inhaling e-cigarette vapor for years.

There is also no real basis for concern that young people — who do not smoke — might decide to take up e-cigs; this is a phantasm raised by those with an agenda against e-cigs.

Why ban a safe and useful product, while leaving the most dangerous product--cigarettes--available on every street corner and in every drug store? That would make no sense. Please do not abandon the over-250,000 New Yorkers who used ENDS to become ex-smokers, to their fate — toxic, lethal cigarettes — which they will resort to if e-cigarettes are banned.

Thank you.

Gilbert Ross M.D. for the American Council on Science and Health

About Face (Eating)

By Jonathan (Josh) Bloom, Ph.D.
June 14, 2012

Medical Progress Today

In 1985 Michael Hovey, an organic chemist at du Pont in Wilmington cooked up a batch of 3-methylfentanyl, an illegal narcotic that is one hundred thousand times stronger than morphine, in his lab, ushering in the modern era of so-called "designer drugs".

After that, things started to go poorly. Getting rid of the stuff, which had a street value of $112 million, proved to be challenging, as evidenced by the fact that he tried to sell it to an undercover FBI agent. Later, out on bail and determined not to go back to prison, Hovey committed "suicide by police."

If this sounds crazy, things have gotten crazier since.

There have been many designer drugs made in the last 80 years, but several years ago, a new one started to become popular. It is called methylenedioxypyrovalerone (MDPV), also known as "bath salts."

If the name sounds familiar, it's because it has been in the news quite a bit lately. The consumption of "bath salts" has allegedly been responsible for a small group of maniacs going around chewing on people's faces, and other assorted violent attacks.

For example, a couple of weeks ago, Miami police shot and killed a naked man who was eating the face of another naked man on the MacArthur Causeway to Miami Beach. Had this happened a few miles further east, it could have possibly been called the South Beach Diet II. There have been at least two similar attacks--one more in Florida and one in Louisiana--all attributed to bath salts.

The name isn't remotely accurate, since bath salts have nothing to do with bathing, and they are not salts. They are synthetic drugs that have structural elements found in both ecstasy and crystal meth, giving them both hallucinogenic and stimulant properties. And in most places, they are perfectly legal--sold in convenience stores

"The consumption of "bath salts" has allegedly been responsible for a small group of maniacs going around chewing on people's faces, and other assorted violent attacks."

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About Face (Eating)

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and gas stations. Sometimes they are sprayed on incense, which is then smoked.

So, how can something like this be so easily abused, dangerous, and legal? Perversely, the answer is innovation.

The designer drug industry has grown and flourished, and its chemists have gotten smarter. It is not difficult to make small changes in the structure of a psychotropic drug and create a different one. It might be better, or worse. One never knows in advance. "Safety" testing is done on the street, so if some of your customers start dropping dead from one drug, it's time to make another.

Law enforcement and designer drug chemists have been playing tag for years, but the chemists hold most of the cards.

This is because there are hypothetically an infinite number of structural changes that can be made to a given street drug.

Some of these substances have managed to skirt law enforcement by virtue of being new. How can you criminalize something that has never been seen before? Or something that hasn't even been made yet, existing only idea in a chemist's mind? This makes regulation of these drugs especially challenging. Countries where bath salts are legal are just now scrambling to add them to lists of banned substances.

Having witnessed (and been part of) the massive research cuts in the pharmaceutical industry, I wondered whether amongst the tens of thousand of unemployed organic chemists in the U.S., some of them might be desperate enough to "Break Bad."

But a call to the DEA revealed otherwise--these drugs are not coming from the United States--they are all coming from China.

As a big fan of irony, I can't help but find all of this somewhat amusing. Not only are we becoming reliant on China to discover and provide our legal drugs, but our street drugs as well. This leaves me speechless.

So, I'm going to stop. It's time to watch the Stanley Cup finals anyhow. I don't want to miss the face-off.

Junk Science Week: Artificial Science

By Elizabeth M. Whelan, Sc.D., M.P.H.
June 13, 2012

FINANCIAL POST

Following New York Mayor Michael Bloomberg's war on sugared beverages, news media seem to have sugar on the brain. An article in Tuesday's New York Times ostensibly discusses the options involved in Choosing a Sugar Substitute. Unfortunately, the colourful feature does little to clarify the issue and far more to confuse its readers.

The article focuses on uncertainties about supposed risks surrounding the major artificial alternatives to sugar. It reports on a "dichotomy of conclusions" that supposedly originate in "the scientific world." Despite a tone of journalistic neutrality, the article essentially gives equal weight to the notoriously alarmist Center for Science in the Public Interest (CSPI) and the authoritative National Cancer Institute (NCI). Worse, the article descends deeper into alarmism by citing the widely disparaged Ramazzini rat "study." It claimed routine use of aspartame posed a cancer risk — a claim that has been debunked time and again.

In typical media style, the rat study is balanced against a large NCI study that found no association between aspartame consumption and cancers in humans. Although another pathologist who has extensively reviewed the safety of artificial sweeteners and found nothing to be concerned about is also quoted, the Times article again turns to notoriously unscientific CSPI, giving credence to its cautionary labelling system.

> "But there is not a shred of evidence that suggests that any of the several artificial sweeteners will pose a long-term risk."

The article cites Dr. Walter Willett, chair of the nutrition department at Harvard's School of Public Health, who raises concerns about long-term health effects of artificial sweeteners, comparing them to the long-term effects of smoking: "It's interesting to keep in mind, if you smoke cigarettes, the lung cancer risk doesn't go up for 30 years," says Dr. Willett. "And that's a really powerful carcinogen. A lot of things don't show up for several decades."

This makes artificial sweeteners look comparable to cigarettes in risk of long-term negative health consequences. But there is not a shred of evidence that suggests that any of the several artificial sweeteners will pose a long-term risk. For a public health professional to introduce such doubt about the safety of artificial sweeteners — and even include a comparison to cigarettes — is just irresponsible and unscientific. By lending equal credence to scientifically unequal sources, the Times just leaves the average reader confused and fearful. Most of the artificial sweeteners available today have been used for decades, and the overwhelming evidence is that they are safe for human consumption.

Junk Science Week: Too Much To Swallow

N.Y.'S Ban On Big Sugary Drinks Lacks Evidence

By Gilbert Ross, M.D.
June 13, 2012

FINANCIAL POST

New York Mayor Michael Bloomberg may have proposed "a ban too far," as his one-time friends at The New York Times put it, when on May 31 he announced plans to ban some sugary beverages exceeding 16 ounces at certain restaurants and other venues.

To be effective in its stated goal — countering obesity — Mayor Bloomberg's plan would depend on several factors functioning in concert:

• Sugar-sweetened beverages would need to be a major factor in weight gain.

• His restrictions would need to reduce fattening ingestions.

• His regulations would need to be amenable to enforcement.

Unfortunately, none of these requirements are even remotely fulfilled.

Take the claim by supposed "nutrition expert" Michael Jacobson of the Center for Science in the Public Interest, who stated in a letter to the New York Post that "[s]ugary soft drinks are the single biggest source of calories in the American diet and are the only food or beverage shown to increase one's risk of weight gain." In fact, a dearth of evidence implicates sugary sodas as a major factor in the decades-long rise in America's BMIs and waistlines.

While U.S. girths increased between 1980 and 2004 or thereabouts, the contribution of dietary sugar and, specifically, sweet sodas remained stable and then declined, as a fraction of the calories consumed. (Since then weights have stabilized, although still at a too-high-for-health level.)

A review of 12 studies published in 2008 in The American Journal of Clinical Nutrition attempted to find a correlation, or link, between beverage consumption and BMI among children and adolescents during the period when weights were increasing the most. This quantitative study found zero association between those parameters: Sugary beverage intake was not linked to weight gain. Another study in the same journal in 2011 showed that overall consumption of "added sugars" — the most common factor mentioned when soda and obesity are targeted — actually declined in the U.S. between 1999 and 2007, the interval of greatest increase in BMI. Another AJCN study from 2012 showed that restricting the variety of nutrient-dense food did not decrease total caloric intake and weight.

> "Sugary beverage intake was not linked to weight gain."

Mayor Bloomberg's plan oddly exempts fruit juices and dairy products (including milkshakes!) from the new rules. Are the mayor and his Department of Health aware that grape juice has a more potent caloric punch than Coke or Pepsi? Do they believe, magically, that the presence of "milk" turns a nutrient-dense ice-creamy treat into a health food? The minuscule amounts of vitamins in fruit juice do not offset the 200 calories per serving.

As for enforcement, I can't imagine how that would work if enacted, as it likely will be — Mayor Bloomberg has decided to bypass consumer and city council approval and go to the city board of health, filled with his own mayoral appointees, for its OK.

People who want to swill soda big-time will find a way to get it. Many will simply buy two smaller drinks — for the price of two, a needless expense. Many who have shared large-sized drinks will now find them verboten. Poorer consumers will, as usual, suffer most.

"But poorer folks are more likely to be obese," some will say. Preventing them from purchasing large-sized drinks may well inspire resentment and an unintended defiance, leading to an increase in consumption. In any event, targeting one particular food as "bad," as opposed to education about balanced nutrition, is bound to be an ineffective weapon against obesity.

The mayor boasted that in New York he has no compunction about rushing in where angels (i.e. authorities in the rest of the nation) fear to tread. But his plan is likely to create a consumer uproar that will undermine future governmental efforts, whatever their merit. Why not educate the citizenry instead? Why not forcefully mandate increases in school requirements for physical education and encourage healthy exercise and relegation of keyboards, remotes and joysticks to occasional use — particularly for young people, to get them outside and moving!

Where does it stop? Why believe soda will be the end of the story, especially if, as most believe, the beneficial effect will be negligible? To avoid failure, maybe Mayor Bloomberg will also ban large pizzas, or steaks, or cheesecake ….

JUNK SCIENCE WEEK:
CT Scans Are The Real Risk, Not Plastics

By Ruth Kava, Ph.D., R.D.
June 13, 2012

FINANCIAL POST

The Institute of Medicine in the U.S. recently released its comprehensive review of environmental causes and risk factors for breast cancer. This should be news: The report, Environmental Causes of Breast Cancer and Radiation From Medical Imaging, published in this week's Archives of Internal Medicine, found that "none of the consumer products (i.e. bisphenol A, phthalates), industrial chemicals (i.e. benzene, ethylene oxide), or pesticides (i.e. DDT/DDE) considered could be conclusively linked to an increased risk of breast cancer." Instead, what the institute found was an association between breast cancer and ionizing radiation, as well as a link between breast cancer and postmenopausal hormone replacement therapy (HRT).

Such findings are consistent with previous studies. And, after concluding that a number of lifestyle factors (such as limiting alcohol consumption and maintaining a healthy weight) "may modestly reduce a woman's risk of breast cancer," the Archives article discusses the disconcerting role that overuse of CT scans plays in the rate of breast cancer. The institute has estimated that "2,800 future breast cancers would result from one year of medical radiation exposure among the entire U.S. female population, with two-thirds of those cases resulting from CT radiation exposures."

The study reasonably states real risk factors and dismisses unfounded scares. Unfortunately, no matter how often the search for "environmental factors," meaning chemicals, is refuted as a cause of breast cancer, those who fear chemicals — especially agenda-driven activist groups seeking donations "to fight breast cancer" — will never let the matter rest.

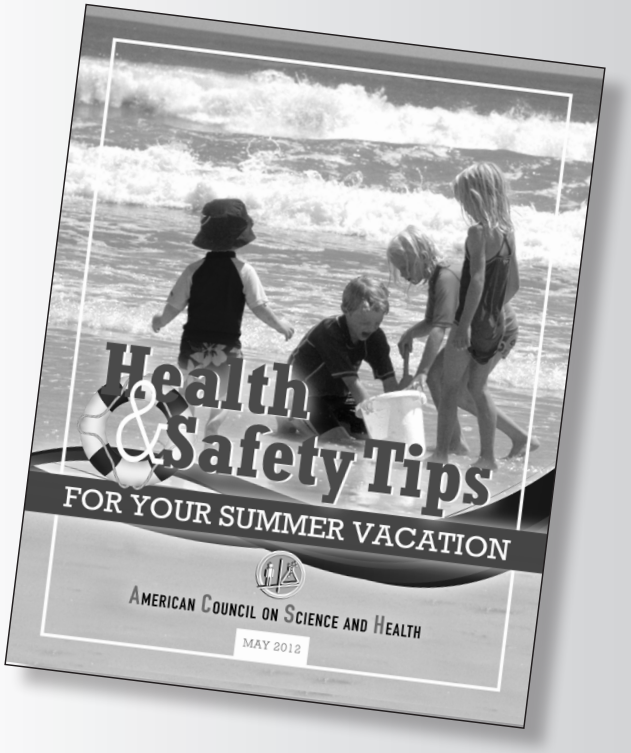
Two other conclusions to be drawn from the study: First, physicians should be aware of the risks and know when a CT is likely to provide information important for making a diagnosis, and when other options are preferable. Similarly, while research continues to support the validity of hormone therapy in menopausal women, doctors should be aware of the risks incurred by extending treatment past the recommended number of years.

New ACSH Publication

Summer Health & Safety Tips 2012

By Ruth Kava, Ph.D., R.D.
June 11, 2012

Whether you are traveling around the world or relaxing at home, a safe, healthy vacation will add to your enjoyment. Here are some health and safety tips to keep in mind when planning your summer vacation.



Welcome To The Dumb Apple

By Jonathan (Josh) Bloom, Ph.D.
June 4, 2012

Medical Progress Today

There has already been so much written about Mayor Bloomberg's latest bewildering attempt to protect us from our fat selves by banning "large" sodas that I don't even want to go there. Nanny state, overreaching government, blah blah blah.

Suffice it to say that New York is looking mighty stupid right now, and if the TV comedians are lining up to make fun of us, it is deserved.

Rather, I thought it might be interesting to examine the "logic" of the proposed law, and suggest a few additional measures that could be instituted.

If the mayor gets his way, you won't be able to buy cups of soda larger than 16 ounces. This is about 180 calories. But a 20 ounce from a supermarket bottle is OK. Without doing the math, I'm going to go out on a limb and predict that the bottle will have more calories. Perhaps the effort required to unscrew the cap offsets the extra calories.

Sixteen ounces of whole milk (300 calories) is fine.

But given the mayor's obsession with reducing obesity, it is clearly better to drink soda than milk since it has about half the calories per ounce. Any argument tossed in here about the nutritional value of milk is irrelevant and obfuscates the point. Calories are calories. When speaking of obesity, the term "empty" calories is empty of meaning.

And as long as we're going to have dumb laws, why not make some more that are even dumber? The possibilities for job creation are endless, and we are always in need of new revenue.

Considering that a hot dog on a bun contains about 350 calories, it is patently obvious that we need to restrict the length of hot dogs to 5 inches instead of 6. The Department of Wiener Compliance would be a welcome addition to our city government. One can only imagine a truckload of inspectors charging into Papaya King armed with measuring tapes. "Lady- step AWAY from the counter!"

Maybe we could borrow a few detectives from NYPD and create a Hamburglary Task Force. Those things are fattening and we'd better regulate them.

Reducing the size of the bottles of sugary drinks sold in supermarkets could be enforced by "Liter Maids," although I don't know if it makes sense to tow away the violators.

Too much cheese on pizza? Big problem, but nothing the "Mozzarella Mobile Unit" couldn't handle. And on Passover they could work overtime on the "Matzoh-rella Mobile Unit."

As the mayor said, "New York City is not about wringing your hands; it's about doing something. I think that's what the public wants the mayor to do."

With due respect, Mr. Mayor, no they don't. They would like to be left alone to enjoy their beverages in peace.

NYC's Soda-Slayer Mayor Strikes Again

Bloomberg Proposes Absurd Effort To Curb Obesity

June 1, 2012

AMERICAN COUNCIL ON SCIENCE AND HEALTH

New York, NY, May 31, 2012 – New York City Mayor Bloomberg's proposed ban on the sale of soda servings and most other sweetened beverages over 16 ounces is the most egregious foray yet in his war on sugary drinks, notes the American Council on Science and Health.

The basis for Bloomberg's proposal is his contention that soda is a major contributor to the obesity epidemic, and therefore should be regulated more stringently than other sources of calories. According to New York Health Commissioner Dr. Thomas Farley, sweetened drinks are to blame for up to half of the increase in New York City's obesity rates over the last 30 years.

But ACSH Executive and Medical Director Dr. Gilbert L. Ross points out that obesity rates have actually stabilized over the past few years, and research demonstrates that there is no correlation between per capita soda consumption and weight.

"There is no solid evidence showing that restricting sodas to a certain size will have the slightest impact on obesity," said Dr. Ross. "In addition, enforcement of such a regulation will not only be extremely complex, but it will also be very costly and difficult to interpret because of the confusing exceptions to the proposed ban."

"Most New Yorkers want the Mayor and his officials to stop micromanaging every aspect of their lives, including what beverages they're allowed to drink and in what amounts," notes ACSH President Dr. Elizabeth Whelan. "This is one of the most frightening proposals to come out of the Bloomberg administration in terms of government overreach. This time he has really gone too far and is sure to rile nearly every New Yorker."

ACSH is a non-profit group based in New York City that is backed by a Scientific Advisory Board of nearly 400 prominent physicians and scientists, and dedicated to ensuring that sound science prevails in our personal and public health policies and decisions.

Treating Recalcitrant Nicotine Addiction: The EBM Way

By Elizabeth M. Whelan, Sc.D., M.P.H., Gilbert Ross, M.D., George Lundberg, M.D.
May 30, 2012

Hello and welcome. I'm Dr. George Lundberg speaking for myself and co-authors Drs. Gil Ross and Elizabeth Whelan of the American Council on Science and Health and this is At Large at MedPage Today.

Willful blindness of our public health officials on tobacco is still killing hundreds of thousands of Americans each year.

Here are the facts:

• There are approximately 46 million tobacco smokers in the United States.

• While three-quarters say they want to quit smoking, and about one-third try to quit each year, fewer than 10% succeed.

• The FDA-approved smoking cessation aids simply do not work: They improve quit rates only minimally, if at all, therefore ...

• About 450,000 American tobacco nicotine addicts die prematurely each year from smoking-related causes.

The means to reduce this public health catastrophe exists: tobacco harm reduction.

The process and benefits of harm reduction are well known: reduce the adverse health consequences of a substance or behavior without demanding complete abstinence (condoms for risky sexual activity, sterile needles for heroin addicts).

By contrast, "abstinence only" demands that users renounce their substance or activity of abuse -- or else.

In a perversion of science-based public health policy, the truth about effective methods to help many more smokers quit has been ignored or even suppressed by our public health authorities.

Tobacco harm reduction involves the substitution of reduced-risk nicotine-delivery products for cigarettes, allowing addicted smokers to quit smoking without forcing them to quit nicotine.

While addiction to nicotine is every bit as strong as that for heroin and cocaine, smoking-related diseases are not caused by nicotine, but by the products of tobacco combustion -- the smoke -- inhaled many times a day.

Just stop the smoke.

Our CDC, FDA, and associations such as the American Cancer Society ignore sound science and epidemiological evidence from Sweden about the documented benefits for smokers of a product called snus.

This type of smokeless tobacco has been shown to increase cessation rates for Swedish men and accounts for the lowest rates of smoking and smoking-related diseases in Europe.

Snus is neither chewed nor spit: it comes in small teabag-like sachets placed between teeth and gum, then discarded after some minutes.

Contrary to official mythologies, snus is not associated with increased risks of cancer: neither oral nor any other type. It does not cause heart disease, and obviously does not contribute to COPD or second-hand smoke.

Another, newer technology which is rapidly attracting desperate smokers is the electronic cigarette (e-cigarette), which delivers nicotine-containing vapor from a cigarette look-alike when puffed.

But again, our guardians of public health have recoiled from the method and attempted to ban them without any conceivable rationale, in another flight from science.

Despite the demonstrated benefits of harm reduction, and the lack of efficacy of the approved pharmaceutical products (such as patches, gum, and medications), public health spokespersons, governmental and private, adhere to the mantra, "there is no safe tobacco product."

While inexcusable, their rationales for such unscientific policies understandably derive from deep-seated mistrust of tobacco companies and their phony promotion of ostensibly "reduced risk" products like "light" or filter-tip cigarettes.

> "Tobacco harm reduction involves the substitution of reduced-risk nicotine-delivery products for cigarettes, allowing addicted smokers to quit smoking without forcing them to quit nicotine."

But this "won't be fooled again" policy -- ignoring the fate of the millions of addicted smokers -- enforces an abstinence only, "quit or die" approach.

This fundamentalism helps no one.

The real victims are the millions of addicted smokers, who deserve to hear the truth about reduced-risk smokeless tobacco. It is time to help addicted smokers get the help they need to quit the death-dealing cigarette.

That's our opinion. We are Drs. George Lundberg, Gil Ross, and Elizabeth Whelan, At Large forMedPage Today.

Dr. Whelan And Dr. Ross Ask The FDA To Reconsider E-Cigarettes

May 29, 2012

To: Center for Tobacco Products, Food and Drug Administration

From: The American Council on Science and Health,
Elizabeth M. Whelan, President
Gilbert Ross, Executive Director and Medical Director

Re: Electronic cigarettes

The American Council on Science and Health (ACSH), a consumer education and advocacy nonprofit devoted throughout our 34-year history to the promotion of sound science in public health policy, urges the FDA to reconsider their current, hyper-precautionary position on electronic cigarettes. The truth is, e-cigarettes have the potential to help the 20 percent of Americans who remain addicted to smoking.

The FDA website states that "e-cigarettes may contain ingredients that are known to be toxic to humans, and may contain ingredients that may not be safe." Our question, however, is: safe compared to what? Those smokers who turn to e-cigarettes are already deeply addicted to smoking tobacco cigarettes. Ideally, e-cigarettes ease the transition from smoking to being tobacco- and nicotine-free. However, even former smokers who substitute e-cigarettes for their tobacco cigarettes make a choice that is far more beneficial to their health than continuing to smoke. While the FDA cautions that e-cigarettes may contain ingredients that are unsafe, we point out that tobacco cigarettes undeniably contain ingredients that are not safe. For someone who is strongly addicted to nicotine, that difference is crucial.

We at ACSH are in favor of truthfully communicating with smokers about the benefits of a harm reduction approach and promoting this as a new paradigm to deal with the unacceptable toll of smoking. The

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methodologies comprising tobacco harm reduction (THR) have significant potential benefits in terms of reducing the serious toll of cigarette smoking; these methodologies supply addicted smokers with the substance they crave — nicotine — but at a much reduced cost in terms of adverse health effects. While we are in full agreement that no form of tobacco use is entirely "safe" (i.e., without an increased risk of adverse health effects), and that therefore all tobacco use should be discouraged, it is still necessary to acknowledge that there are 46 million addicted adult smokers in our nation. The problem remains that, while almost three-quarters wish to quit, and almost one-half do indeed attempt to quit each year, well under ten percent succeed. One reason for this abysmal "success" rate is that the methods approved by the FDA (including the nicotine patch, gum, inhalers, and pharmaceuticals such as Zyban and Chantix) and promoted by the official public health authorities and the large nonprofits, are simply not helpful to the majority of those who try them.

> "A product that can end a smoker's exposure to the carcinogenic products in tobacco smoke is not one that can be dismissed lightly."

E-cigarettes do help people quit. The increasing evidence from anecdotal reports and clinical studies shows that addicted smokers are significantly more likely to quit cigarettes when they are aided by e-cigarettes as opposed to those cessation products approved by the FDA[1]. Furthermore, the FDA's warning that the chemicals in e-cigarette vapor may be "unsafe" or "toxic" is not backed by evidence that trace amounts actually cause any harm; in fact, similar traces of these same "carcinogens" have been detected in other FDA-approved cessation products such as nicotine patches and gum. The difference seems to be that e-cigarettes actually succeed in getting people to quit smoking.

A product that can end a smoker's exposure to the carcinogenic products in tobacco smoke is not one that can be dismissed lightly. It should not be rejected based upon ideology or unscientific extrapolation and insinuation. This is why, instead of warning the public about unlikely risks associated with e-cigarettes, the FDA should also consider their benefits: taking steps that encourage further study and better regulation of these products will be

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Dr. Whelan And Dr. Ross Ask The FDA To Reconsider E-Cigarettes

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more advantageous to everyone involved. At the very least, the FDA's position should be expectant, neutral, rather than dismissive.

We at ACSH firmly believe that the more comprehensive the investigation, the more likely it is that reasonable people will come to understand that the official policies of adhering to a current attitude of "quit or die" does little to affect the continued toll of over 400,000 smoking-related deaths each year. This is no longer an acceptable position from a public health perspective, which is why we ask you to reconsider your negative stance toward e-cigarettes.

Thank you for your consideration.

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Why I Don't Write About Pottery From The Ming Dynasty

By Jonathan (Josh) Bloom, Ph.D.
May 17, 2012

Medical Progress Today

Sometimes it's good to recognize your limitations.

For example, I could describe how DNA works, or how to make crystal meth, poison your neighbor or blow stuff up. I won't, but I could. And I'd know what I was talking about.

Perhaps I could also write something about teapots from the Ming Dynasty if I read about it on Wikipedia, but in reality I wouldn't know one if it fell off the Chrysler Building onto my head.

Nicholas Kristof is a columnist for The New York Times. As such, he has written about a wide range of topics such as politics, human rights, poverty, foreign affairs, and economics. He does this extremely well, as demonstrated by his multiple awards, including two Pulitzer Prizes. He also appears to be nothing short of brilliant, and an all-around good guy as well.

But sometime prior to May 2nd, when his last column, "How Chemicals Affect Us" was published, he may have been walking a little too close to the Chrysler Building.

Kristof's formal training is in law and foreign languages. Notably absent are: chemistry, toxicology, pharmacology and reproductive biology. Which is a shame, because that is what his entire piece was about.

And it showed. Kristof rattled off a bunch of mostly unrelated claims, that, to a non-scientist would appear very scary. These involved the usual suspects, such as increasing cancer rates, low sperm counts and a host of others. But once you scratch beneath the surface, a very different story arises.

The column makes generous use of the nonsensical term "endocrine disruptor," something that is supposed to interfere with our endocrine system--the incredibly complex series of glands that produce hormones. "Disruptor" is a nice scary sounding word, but scientifically

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meaningless. What exactly do endocrine disrupters disrupt? And how?

In your body, hormones, whether synthetic or natural, interact with receptors on particular cells and elicit a response. Two common natural hormones are estrogen and testosterone, both critical to sexual development. Drugs frequently interact with hormone receptors and either amplify or diminish a physiological process. The breast cancer drug Tamoxifen blocks the estrogen receptors in breast tissue, suppressing the growth of cancer cells that are dependent on estrogen to replicate.

Once in a while something will go very wrong.

A particularly awful example of this was diethylstilbesterol (DES), a drug that until 1971 was sometimes given to pregnant women since it was thought to prevent miscarriages and premature deliveries. But its use was discontinued after it was discovered that it caused a rare cancer and reproductive abnormalities in the daughters of mothers that took the drug. Sons had different and less serious conditions, but by any measure, this was a drug disaster.

Thalidomide, used for morning sickness more than 50 years ago was found to be a potent teratogen-- a chemical that can cause severe developmental problems. Children of mothers that took this drug often were born with undeveloped arms or legs, or sometimes none at all.

Even today, teratogenic drugs exist, but they are treated quite differently. Accutane, used for severe acne, is a powerful teratogen. However Roche, its maker, is so careful that it doesn't get near a pregnant woman that a pregnancy test is required every month before it can be purchased and the women needs to sign a form swearing she's using at least two methods of birth control.

It is very rare, but still possible for these unforeseen side effects to occur; however, modern preclinical assays make this much less likely for drugs.

But can you take a serious teratogen like DES or thalidomide, which were given in therapeutic quantities to pregnant women, and claim any relevance to trace chemicals found in everyday life?

At this point it becomes clear that Kristof is entering the Ming Dynasty. He equates DES with a chemical called bisphenol-A (BPA), a component of many plastics that has been in use for more than 50 years. Very small amounts of BPA leach out from the plastic, which has caused it to be tested a bazillion times, with no evidence of human harm. Sometimes, if you shovel enough into a rat, bad things can happen, but you better have a big shovel. Even the FDA has said, on several occasion and despite withering activist pressure, that it is safe as used, a decision called "cowardly" by environmental groups that wanted it banned.

But what does giving mega-doses of BPA (or anything else, really) to a mouse or rat have to do with the real world where we take in (and rapidly excrete) tiny quantities of it?

Since BPA plastics are used to seal food cans, among other things, virtually all of us have some measurable amount of it in our bodies, albeit in miniscule amounts. Just like we have thousands of other chemicals, both synthetic and natural, floating around in there.

This fact has led groups and individuals to try to pull the wool over the eyes of those lacking a science background--that is, they imply or just assert that the presence of a chemical is necessarily related to any health consequences from it. This contradicts one of the tenets of toxicology--the dose makes the poison. It may sound trite, but it's just as true as ever.

If this were not the case, one would expect to be seeing massive health consequences for the estimated 80 thousand chemicals used in modern life today. So where are they?

I have no idea. In fact, the incidence of almost all cancers in the U.S. has been slowly drifting downward over the last thirty-five years according to the American Cancer Society. And the myth of declining sperm counts was thoroughly debunked in a Columbia University paper in 2008 and several other large epidemiological studies. The research alleging declining sperm counts used to reach this "conclusion" was flawed.

All of this brings up some practical matters. How is testing 80 thousand chemicals going to work? Should we ban all 80 thousand until they are first tested? What will it cost? Who is going to do it, and how will they measure whatever property they are looking for? At what dose? In what animal? And please believe that even if this monumental task were ever completed, there would be no shortage of borderline or ambiguous data with no clear answer. And it will still be animal data, which may or may not have any relevance to human health. Then what? How can anything useful ever come out of this?

Kristof "takes a cue from [his] experts," but I have to wonder about his choices. One of them, Dr. John Peterson Meyers, the chief scientist at Environmental Health Sciences is so afraid of BPA that he and his family stopped buying any canned food and refuses to touch receipts (many of which have traces of BPA) from gas stations or ATMs. Kinda makes me wonder if you could screw with his head by giving him a whole bunch of really bad birthday gifts and include the gift receipts, knowing he couldn't return any of them.

In the end, this is all silly. People are not dropping dead from ATM receipts or canned soup. Cancer is still cancer, but rather than the "cancer epidemic" we hear so much about, there is actually less of it than there used to be, despite the aging of our population. And if you should be in the mood to count your sperm, they will be fine too.

Health doesn't come from eliminating everything that might conceivably be unsafe from the environment. It comes from not smoking, getting vaccines, wearing seatbelts, staying in shape -- and a whole lot of luck.

Tea time.

Me-Too? Says Who?

By Jonathan (Josh) Bloom, Ph.D.
May 10, 2012

Medical Progress Today

A small study recently conducted by Abbott, a major pharmaceutical company, seems to indicate that they have discovered the Holy Grail of hepatitis C therapy--not only curing the disease, but also doing so without the use of interferon. This is both an enormous medical advantage, and also serves as a good example of why those who use the term "me-too" drugs in a pejorative sense to describe second or third generation medicines have no idea what they are talking about.

As I noted last year, scientists at Abbott seemed to be on the cusp of being able to duplicate the AIDS cocktail approach for hepatitis C--and then some--having advanced both a protease inhibitor and a polymerase inhibitor to the point where it was reasonable to run trials with the intent of eliminating interferon from current hepatitis treatment regimens. (Interferon, which must be given intravenously, is exceedingly difficult for patients to tolerate, causing severe depression, flu-like symptoms, nausea and fatigue, forcing many patients to discontinue treatment.)

"When given a four drug cocktail, patients who had not been previously treated showed an astounding 95 percent cure rate (being virus free 6 months after cessation of therapy)."

The trial results were nothing short of astounding.

When given a four drug cocktail, patients who had not been previously treated showed an astounding 95 percent cure rate (being virus free 6 months after cessation of therapy). In more difficult cases, where patients had already tried, but failed other therapies, 47 percent of these people (previously considered virtually untreatable) were still be cured. Interferon was not used at all. Is this innovative? After all, there are already two HCV protease inhibitors on the market from Vertex and Merck. So why keep going? Well, as it turns out, there are plenty of reasons, despite the constant braying of perennial critics like Marcia Angell of the Harvard School of Public Health. Angell, and others, who criticize so-called 'me-too' drugs as being non-innovative are displaying their ignorance about pharmaceutical matters. The second or third drug in a new class is often superior to the original. This can result in enormous medical advantages, despite what vocal critics wrongly maintain.

The HCV discovery model closely followed that used to discover the HAART (highly active antiretroviral therapy) drugs that revolutionized the treatment of HIV. The prototype HAART drug was Invirase (saquinavir), an HIV protease inhibitor (PI) launched by Roche in 1995. This marked the beginning of a decade of medical advances that were so remarkably successful that AIDS has mostly become a manageable chronic illness, largely out of the headlines.

But it sure wasn't Invirase that was responsible. Even though Invirase worked, all sorts of problems, including gastrointestinal (GI) toxicity and poor bioavailability (meaning little of the administered dose was effectively circulating in a patient's bloodstream), plagued it. As a result, possibly the most important and innovative new drug in decades isn't even used any more.

But there are 9 other PIs available, and they sure as heck work. During the ten-year span in which these "me-too" drugs were being introduced, some were better--more potent and less toxic, each of these giving HIV a good stiff kick in its own way.

Does Dr. Angell really believe that we would have been better off without the ninth (and now preferred) HIV PI? Or how about the fifth (and most potent) non-nucleoside reverse transcriptase inhibitor (NNRTI), or the fifth nucleoside reverse transcriptase inhibitor? Because the medicines from this group of "me-too drugs" make up all of the preferred HIV cocktails at this time--the same cocktails that have not only tamed AIDS, but are now so good that they can prevent transmission from HIV-positive males to uninfected females 96 percent of the time, as demonstrated by studies last year in Africa. If you're in the Ivory Tower neighborhood, maybe you should ask Dr. Angell whether drugs that are putting a huge dent in two of the most important viral infections in the world, AIDS and hepatitis C, and the companies that discovered them, should be deemed useless, along with the tens of millions of lives that they save, just because they are "me-too" drugs. Patients fighting HIV and hepatitis C know that the world would be far worse off without these medicines. What do you think?

Me too.

Josh Bloom is the director of chemical and pharmaceutical sciences at the American Council on Health and Science and a contributor to MedicalProgressToday.com.

Dr. Whelan Urges Kansas To Consider Tobacco Harm Reduction Study

May 2, 2012

To: The Kansas House of Representatives
Committee on Federal and State Affairs

From: The American Council on Science and Health
Elizabeth M. Whelan, President

Re: Support for Resolution No. 6026, to direct the KDHE to investigate a study of tobacco harm reduction

The American Council on Science and Health (ACSH), a consumer education and advocacy nonprofit devoted throughout our 34 year history to the promotion of sound science in public health policy, urges the Kansas House of Representatives to pass Res. 6026, directing the Kansas Department of Health and the Environment (KDHE) to undertake a one-year analysis of Tobacco Harm Reduction (THR).

Our own studies of this subject (1, 2), published in a peer-reviewed academic journal, as well as many others, have proven to our satisfaction that the methodologies comprising THR have significant potential benefits in terms of reducing the tragic toll of cigarette smoking by supplying addicted smokers with the substance they crave--nicotine--but at a much reduced cost in terms of adverse health effects.

While we are in full agreement that no form of tobacco use is entirely "safe"--i.e. without an increased risk of adverse health effects--and that therefore all tobacco use should be discouraged, it is still necessary to acknowledge the fact that there are 46 million addicted adult smokers in our nation, about 20% of the total population. Further, while almost three-quarters wish to quit, and almost one-half do indeed attempt to quit each year, well under one-tenth succeed. One reason for this abysmal "success" rate is that the methods approved by the FDA (including the nicotine patch (NRT), gum, inhalers, and pharmaceuticals such as Zyban and Chantix) and promoted by the official public health authorities and the large nonprofits, simply fail to help smokers quit.

The established authorities' positions on using reduced risk products to deliver adequate nicotine levels to requite smokers' cravings and help them get off deadly cigarettes is based on long-held, formerly legitimate but now obsolete hatred and mistrust of tobacco companies. Given the current stringent regulatory oversight and the clear downward-trending cigarette sales along with the irrefutable evidence of "the Swedish Experience," which illustrates how Swedish men have shifted their tobacco use pattern from lethal cigarettes towards much safer "snus" (smokeless tobacco in small teabags), it is in tobacco companies' interests as well as public health's for them to market reduced risk products. They couldn't get away with the nefarious behaviors of the 20th century, even if they had such an inclination.

Those who support Resolution 6026, including ACSH, merely ask the Kansas legislature to initiate a science-based study of the subject. We would not expect a commitment based upon our say-so, even based on our scientific investigations, and we merely encourage your health department to conduct your own studies. This should include not only snus-type smokeless tobacco aimed at helping addicted smokers quit cigarettes, but also the newer products such as dissolvable tobacco and electronic-cigarettes (e-cigarettes). We firmly believe that the more comprehensive the investigation, the more reasonable people will come to understand that the official policies of adhering to "there is no safe tobacco product, so abstinence is the only answer" amounts to a "quit or die" position, the status quo, with the ongoing toll of over 400,000 smoking-related deaths each year. This is no longer an acceptable position from a public health perspective, and we hope you will agree that such a study is desperately needed, indeed long overdue.

Thank you for your consideration.

Elizabeth M. Whelan, Sc.D., M.P.H.
President
The American Council on Science and Health

How Sweet It Isn't (Facts And Fears)

By Ruth Kava, Ph.D., R.D.
April 26, 2012

Some pundits concerned about health conditions linked to dietary excess are proposing draconian fixes. The problem, though, is that these drastic fixes are broken to start with. Perhaps most wrong-headed of all is the argument made for regulating the consumption of foods with added sugars as though they were cigarettes or alcoholic beverages. Sin taxes, age restrictions, food stamp limitations: as with alcohol and tobacco, so with added sugar, goes the logic.

The anti-sugar party line, recently amplified by Dr. Robert Lustig's commentary in Nature, is that such foods are "addictive" and "dangerous" — just like alcohol and cigarettes. Lustig and his followers advise us to avoid these "toxic foods" altogether. And The New York Times' Mark Bittman echoes him, reminding us that there is "no nutritional need for foods with added sugar."

While this latter observation is true enough, what such a critique neglects to mention is that there is no nutritional need for any particular food — with or without sugars of any kind. Indeed, after infancy, there is no essential food at all. What is essential are nutrients: vitamins, minerals, fatty acids, and proteins. And as long as these needs are met, it doesn't particularly matter whether a given vitamin comes from salmon or from fortified breakfast cereal—with or without added sugar.

Furthermore, these would-be sugar police seem to forget that we don't eat solely to meet nutritional needs. A range of cultural practices, social settings, and personal preferences inform our food choices. Suggesting that governmental regulation can surmount this variety of factors and result in a better diet seems either naïve or, more likely, based on some ideological inclination rather than

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nutritional concerns.

Even if we did agree to such regulation, how would it be enacted? Would children no longer be allowed their chocolate milk—even the low fat variety containing all the protein and calcium of the unflavored product—because it contains added sugar? If foods with added sugar were lumped onto the list of items that can't be purchased with food stamps — as more than a few of these prohibitionists have proposed — imagine sorting through every new grocery item that comes down the pike. And one wonders whether taxes on sugar-sweetened foods would go toward the extra tax dollars needed to enforce the age-restriction on soda?

The regulation of cigarettes and alcohol is not an adequate model for policies applied to foods. Cigarettes are both addictive and without any redeeming health value whatsoever, and alcohol—when used intemperately — can lead to intoxication or organ damage. But while it's possible to eliminate these products from one's regimen, the same cannot be said of food.

In truth, the most dangerous aspect of foods in our well-supplied culture is consuming too much of them. Even if foods with added sugars were eliminated completely, there's no guarantee that people would become more judicious in their food choices or about the amount of food they consume. And there's the rub — in the midst of an unprecedented abundance of food choices, many consumers don't understand how to choose healthful diets. Regardless of whether one shops at the most pristine of farmers markets or the local supermarket, choices must be made. While it's easy to demonize individual foods or — in this case, ingredients — it's not so easy to regulate the multitude of individual choices that make up any one person's diet.

"In the midst of an unprecedented abundance of food choices, many consumers don't understand how to choose healthful diets. Regardless of whether one shops at the most pristine of farmers markets or the local supermarket, choices must be made."

Instead of enacting punitive regulations, if we really want people to make more healthful choices, we need to inform and empower them to make choices that are meaningful to them. School-related programs that educate children and parents about exercise and healthful eating that's affordable to them are a more productive, long term approach. Such efforts will ultimately go further than simply dictating what people can and cannot buy.

Just saying "no" may work with tobacco and alcohol, but we need a different approach when it comes to food.

Silence About Harm Reduction Is Killing Smokers

By Elizabeth M. Whelan, Sc.D., M.P.H.
April 17, 2012

AMERICAN COUNCIL ON SCIENCE AND HEALTH

Quit or die.

That's the message cigarette smokers get from the public health community.

But in fact, smokers who have trouble quitting have some rarely mentioned alternatives to total abstinence from tobacco: it's a method of intervention called "tobacco harm reduction."

Some 450,000 Americans die prematurely each year because they smoke. Yet if cigarette smokers would just switch to safer products, we could cut the yearly number of tobacco-related deaths to 10,000 or less.

Tobacco harm reduction converts smokers to these safer products — reduced-risk nicotine products — thus curtailing their smoking without forcing them to give up the nicotine they crave. And this is key. Nicotine, while highly addictive, is not in itself harmful. Cigarette-related diseases are caused by the inhalation of smoke — specifically, the products of combustion. The nicotine in cigarettes is not what causes cigarette-related diseases.

Given that, there are a number of harm reduction options:

Products called snus and pellets allow nicotine to be absorbed through the mouth. When the nicotine has been absorbed, the user simply discards the small, teabag-like sachet of snus; the pellets dissolve without any residue. Neither of these options involves the dipping and spitting associated with chewing tobacco — which, unfortunately, is still what most people think of when they hear the words "smokeless tobacco."

Although there is a prevailing belief that oral uses of tobacco cause mouth and throat cancer, there is very little evidence to support such a claim. Whatever health risks might be posed are truly minimal compared to cigarette smoking.

Observations in Sweden, for instance, confirm the relative health benefits of snus. There is a major disparity in smoking rates between Swedish men and women. For the last 50 years, lung cancer mortality among Swedish women has been among the highest in Europe; not surprisingly, many Swedish women smoke cigarettes. Conversely, most Swedish men who use tobacco use snus, causing them to have the lowest rate of lung cancer among men in the European Union.

The electronic cigarette, or e-cigarette, is another option for smokers who would like to quit. E-cigarettes are battery-powered devices that vaporize a mixture of propylene glycol (an FDA approved substance), water, nicotine, and flavorings. They are activated when the user inhales — and gets a dose of nicotine in the process. New—and very sophisticated—forms of the e-cigarette are now in development stages at major tobacco companies who, regardless of their past duplicity, see the writing on the wall as fewer Americans smoke and more and more try to quit.

What snus, pellets, and the e-cigarette have in common is that they are clean nicotine delivery systems. They give smokers the nicotine they crave, minus the devastating health consequences of smoking.

Given the efficacy and safety of these life-saving methods, you might assume the FDA and traditional anti-smoking groups would be singing the praises of harm reduction methods, encouraging smokers to make the switch.

But they are not. Indeed, they actively reject the use of snus, nicotine pellets, and e -cigarettes, instead repeatedly asserting "there is no safe alternative to smoking." The result of this rejection of harm reduction? Hundreds of thousands of smokers die unnecessarily each year.

Dr. Whelan is the president and founder of ACSH.

Cutting Off Your Face To Spite Your Face

By Jonathan (Josh) Bloom, Ph.D.
April 12, 2012

Medical Progress Today

The critical shortage of generic hospital drugs has been big news for about a year. Much has been written about it, yet many are still not aware of it.

So, I thought that yesterday's very thorough and sobering story in the Washington Post on the topic, although profoundly upsetting, might make some people understand how high the stakes are, and what are the real causes behind the problem. It's not that complicated--price controls coupled with quality control issues has caused many generic companies to conclude that they cannot make even a reasonable profit on certain drugs, so they have halted production entirely. This leaves us with a national emergency on our hands.

This problem has absolutely nothing to do with brand named expensive drugs, the ones that are sold by large drug companies, who are somehow being blamed for this. One might hope that a few more people would understand this, put away their hatred for drug companies for a moment, and think. This problem originated mostly in Congress, when they passed a 2003 law placing price caps on generic drugs for Medicare. The number of drug shortages is five-times higher since then.

Some people get this, but many do not, as evidenced by the comments following the Post article.

roberto3: "there seem to be plenty of drugs for erectile dysfunction, calcium citrate etc that the Pharma is actively peddling..? Why not go over their heads and get the FDA to import these vital drugs anyway?" Well put, Roberto. But would

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you please tell me what the hell you're talking about?

CalypsoSummer: "many of these drugs are patented. We know what "patented" means, don't we? It means that only one (1) company can legally make them." Good point, except 100% wrong. Go back and read the article.

HGF78: "If some die so the drug companies can keep increasing quarterly profits, so be it. This is letting the "free market" decide. You are also killing 2 birds with one stone, no need for those death panels. Those that cannot pay are just eliminated." Uh, HGF, get help. Now.

Woodyag: "Nothing improves profits like scarcity. Wonder if there might be any connection." Maybe, but not between the lobes of this guy's brain

funfun881: "Medicine is highly regulated but when drug companies discontinue cheap drugs to force you to use more expensive ones, this is NOT regulation---it is theft. The solution is simple: let government make the drugs which free enterprise, out of its own free will, will not supply. Hate to break this to you, but cheap drugs arise when patents run out. If you don't like this, I suggest trying to speak to George Washington and Alexander Hamilton. Patent rights are written into the Constitution. And you want the government to make our drugs. Swell idea. Yeah- there will never be shortages then.

But, at least someone got it:

LouisL:The Drug Co's aren't perfect but have saved millions, me & my sister for ex[ample]. Some safety regs are necessary, but unless we make HealthCare market friendly, Shortages & Rationing are our Kid's Future. - except for the Political Class, (see USSR) Louis- thanks for nailing it. No- drug companies are not perfect, but they have saved millions of lives.

Do people really hate drug companies so much that they want them to fail, even though this mind-set is self-defeating? I guess this been hammered into our heads by the press and pandering politicians so that most people see is an evil empire. It might get some reporter a prize or an empty-headed political candidate something to talk about, but in the end, as the health of drug companies fails, so will ours. I suspect Louis knows this.

The Ugly Toll Of Health 'Efficiency'

By Jonathan (Josh) Bloom, Ph.D.
March 28, 2012

Medical Progress Today

As the Supreme Court hears arguments this week on whether the ObamaCare law is constitutional, here's something to think about — a possible real-life example of what all that "death panel" talk really means.

The Advisory Committee on Immunization Practices — a division of the Centers for Disease Control — last month quietly refused to vote on whether to recommend Prevnar 13, a vaccine against streptococcal pneumonia, for adults 50 and older. That decision likely means tens of thousands of additional deaths.

ACIP review is another hurdle for vaccines (not required of traditional drugs) after Food and Drug Administration approval. The committee, 15 experts in immunization appointed by the secretary of Health and Human Services, develops recommendations for vaccination schedules and dosages for pediatric and adult use. Or not.

The vaccine is already recommended for children, mind you, and the Food and Drug Administration has approved it for older people. (Vaccines are unique in US medical regulation in needing ACIP as well as FDA approval; more on that below.)

The FDA OK'd Prevnar on the basis of data that show that it elicits a stronger immune response and is effective against a broader spectrum of bacterial infections than previous vaccines.

Since Streptococcal pneumonia is responsible for 300,000 hospitalizations and 25,000 deaths a year, ACIP recommendation ought to be a no-brainer.

Yet when the drug's maker, Pfizer, sought ACIP's endorsement, the committee for the first time ever refused to schedule a vote — despite three meetings over the course of a year during which the vaccine was discussed.

One of the experts present told me "there wasn't a single member of the panel that wouldn't take the new vaccine." Yet they won't recommend, even though it's already used on adults in a number of European countries — including Greece, hardly the bastion of socio-economic acumen these days.

So what's going on here?

I'm told that ACIP cited various reasons for waiting, including Pfizer's supposed failure to meet new protocols and a desire to see the results of a European study. But neither excuse is persuasive. It looks a lot more like an improper focus on cost.

There's nothing inherently wrong with determining whether a new therapy will be cost-effective — that is, would eventually save more money than it costs. But vaccines are extremely cost-effective, typically saving 10 times their expense per patient.

A recommendation from ACIP means that most insurance plans will cover a vaccine — and that Medicare must automatically pay for it.

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The Ugly Toll Of Health 'Efficiency'

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At $97 per dose, the cost of vaccinating the 40 million adults 65 or older in the United States would be several billion dollars. Holding off would be a big short-term savings for Medicare.

The long-term expense would be far greater, but let someone else worry about that.

One quote from the last ACIP meeting is as revealing as it is chilling: "The working group plans to continue discussions regarding whether [Prevnar] should be recommended for adults 50 years of age and older as additional data on herd effects and efficacy against pneumonia become available."

"Herd effect" refers to the fact that when enough of the population is vaccinated, the disease in question becomes less prevalent, thus protecting the rest of the herd — those who are unvaccinated.

So APIC is effectively pondering this experiment: We already vaccinate kids; let's wait a few years and see how many seniors die.

If I were 65, I wouldn't like this experiment one bit. It will take years to determine the full extent of the herd effect. Perhaps 100,000 unvaccinated seniors will die waiting for the answer.

The "death panel" discussions of 2009 were blatantly nonsensical. Anyone with half a brain knew that the government wouldn't be hauling Granny off in a windowless van because she needed a hip replacement.

On the other hand, every year that this vaccine is unavailable to Medicare recipients, thousands of them will die unnecessarily.

If this is the way our government really intends to cut America's medical costs, this story is not really about a vaccine at all.

The Land Of The Free, And The Home Of The Neurotic

By Jonathan (Josh) Bloom, Ph.D.
March 20, 2012

Medical Progress Today

Many things in life make me crazy. It doesn't take much, as anyone that knows me will confirm. So, it is no surprise that the feature article in last week's Times called "Is It Safe to Play Yet?" did the job. But it happened before the end of second sentence. And that takes something special.

Things certainly have changed since I was a kid. People had a slightly different idea of the meaning of the word "safe." Biking to school (no helmet) through a Superfund toxic waste site with a bottle of Jack Daniels in one hand and boa constrictor wrapped around your neck seemed perfectly fine. Who knew? Perhaps we are much safer now. But also much less sane.

The Times article first described the efforts made by a pregnant woman to prevent her baby from being exposed to any chemical. So, she tossed out pretty much everything in the house, including her makeup, shampoo and detergents. She was even worried that the plastic stickers decorating the nursery were toxic and irritating to the lungs, because they were made out of polyvinyl chloride (PVC). Except it's all wrong.

A little fact check: Vinyl chloride is a toxic, irritating gas used to make PVC. I know this. I got a whiff of it a few times during my career--most unpleasant. But vinyl chloride and polyvinyl chloride are not even remotely the same, except for the names. PVC is a white powder that can be made into all kinds of plastics, including your plumbing, vinyl siding, and a good deal of your car. It has been in use since the 1950s. It is impossible to avoid, which is fine, since it is harmless.

Naturally, the more the woman read, the scarier every label got, leading her to the internet, which, in turn led her to the web site of the Environmental Working Group (EWG)--a very vocal and extremely activist organization, that appears to be against all physical matter on earth.

I don't know what their charter says, but I suspect it looks something like this:

1. Assume that chemicals cause cancer unless you can prove that they don't.

2. It is not possible to prove that a chemical doesn't cause cancer.

3. See #1.

And this woman is not alone. People who apparently listen to too many TV celebrities are flocking to sites like healthychild.org, and healthystuff.org, to ensure that their babies are exposed to absolutely nothing that sounds threatening. Some of the big no-nos these days are rubber ducks, perfume, plastic and steel (!) utensils, pajamas and frying pans.

Even cribs are now dangerous--untreated, "formaldehyde-free" wood cribs handmade by the Amish are the latest rage. Sorry guys, but the amount of formaldehyde coming out of a normal crib, if any, would be so miniscule that it could never be measured. And even if a smidgen of formaldehyde somehow made it into your body, it is gone in 5 minutes.

Some environmental changes have been real success stories, like removing lead from gasoline. That was a real risk. But this notion that we are constantly are being bathed in toxins, and that all accumulate in our bodies and do some kind of harm is farcical. The reason that miniscule

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When Is A Drug A Drug?

By Jonathan (Josh) Bloom, Ph.D.
March 16, 2012

According to the FDA, a drug is a substance (other than nutrients) intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or function of the body. Seems clear enough -- that is, until politics and big money get involved.

With the aid of a 1994 law crafted by Senators Orrin Hatch and Tom Harkin, the mega-billion dollar supplements industry has done a splendid job of obfuscating this definition. By taking advantage of consumer's scientific naïveté and some legislative doublespeak, the supplements industry has successfully perpetuated the myth that what it is selling is drug free and safe. This couldn't be more wrong.

It's a timely topic, given that the U.S. Army is now investigating whether the deaths of two young soldiers last year were related to the "dietary supplements" called Jack3d and OxyElite Pro, which they had taken.

But what the soldiers actually took is an amphetamine-like synthetic chemical called dimethylamylamine, a stimulant with multiple cardiovascular and central nervous system effects. It alters the function of the body -- so it's a drug. It is also a banned doping agent used by athletes, but you can buy it at the Vitamin Shoppe or GNC.

"Health" stores have huge displays of similar products -- drugs that are falsely labeled as supplements. Another example is DHEA, a steroid that's converted in the body to various anabolic and neurohormonal steroids, all having profound physiological effects. Is this a drug? You bet.

Another supplement, the subtly named RockHard Weekend, contains extracts from certain bark and roots, including the always-popular Horny Goat Weed. There must be dozens of chemicals in the bottle -- but does anyone know what all of them are, let alone whether they're safe or effective? No.

The mindset exploited by this industry is so pervasive that many people believe supplements-- especially those derived from plants -- can do no harm. This is utterly false. Plants do not exist to benefit humans--their purpose is to survive and reproduce; accordingly, many plants have evolved ways of making some really good poisons to avoid being eaten.

> "The mindset exploited by this industry is so pervasive that many people believe supplements -- especially those derived from plants -- can do no harm."

Hemlock, the poison that killed Socrates, comes from an herb. Strychnine (rat poison) comes from the Nux vomica tree. Ricin, one of the most toxic substances on earth, comes from castor bean roots. And even legitimate plant-derived drugs, such as digitalis and taxol, are sufficiently toxic that their use must be carefully controlled.

So why are companies allowed to sell drugs under the guise of supplements that aren't even subject to minimal FDA oversight? This is where the double-speak comes in.

The Hatch-Harken law provided the supplement industry with a legal but anti-scientific end-run around the FDA by introducing some terms that permitted the marketing of unregulated drugs. As long as they were called "dietary supplements," and made no specific health claims, they could be sold. But these "restrictions" are wholly disingenuous.

Does anyone really believe that anabolic steroids and stimulants should be labeled as supplements? Exactly what are they supplementing? By this logic, just about anything you can swallow could then be called a "dietary supplement."

And to avoid making medical claims, the meaningless term "supports," as in "supports heart health," was concocted. Please. When you see "supports" (wink, wink), just mentally substitute "this will cure." Duplicity at its finest.

The FDA is now attempting to establish some control over supplements, although it is not remotely sufficient. For instance, the regulations would require that all new supplements "can reasonably be expected to be safe." Are they kidding? Pretty low standards, if you ask me.

Pharmaceutical companies spend hundreds of millions of dollars to determine the safety of new drugs, only to have many of them fail anyhow due to unexpected side effects. But manufacturers of supplements are not held to any regulations that even approach this level of scrutiny.

Supplement regulations are driven by money and sleight-of-hand, not science. But drugs are drugs. They should all be treated the same.

The Land Of The Free, And The Home Of The Neurotic

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amounts of chemicals can be measured in our bodies is due to better analytical techniques--not a wholesale poisoning of the American public.

My current favorite fad is the obsession with "green," non-toxic detergent made from baking soda and vinegar. When the two are mixed another chemical is formed called sodium acetate. Is that dangerous? No. But it doesn't clean anything either. And if you're tempted to make some, consider the experiment below (not recommended):

1. Take a half-full bottle of vinegar
2. Pour in a bunch of baking soda
3. Close bottle and shake thoroughly, making sure you hold it really close to your face
4. Retrieve your head from the tree above you

Your kids are going to spend a lifetime being exposed to chemicals: auto exhaust, smoke, soot, chlorine, soap, perfume. They will be fine. Just calm down. The groups with a vested interest in keeping you afraid are not a credible source of information.

Two Faces Of Cancer

By Jonathan (Josh) Bloom, Ph.D.
March 15, 2012

Medical Progress Today

According to a paper in yesterday's Journal of Clinical Oncology, the 5 year survival rate of children with acute lymphoblastic leukemia (the most common form) has continued its upward trajectory, and now stands at 90 percent--fairly amazing considering that it was almost always fatal as recently as the 1960s.

This should not be taken as evidence that the end of cancer is around the corner--it is not. Although there have been a few cancers that are either curable (testicular, for example), preventable (cervical) and more treatable (breast), progress against the disease has, for the most part, been incremental and slow. A recent paper in the New England Journal of Medicine offers an peak into why this may be.

When Dr. Marco Gerlinger of the Cancer Research UK London Research Institute and his group examined the genetic makeup of kidney tumors and compared it to that of metastases from the same tumor, they found unexpectedly large differences between the genetic makeup of the original tumor and the cancer that had metastasized. Oncology researchers have long known about mutation of cancer cells, but until this week they didn't appreciate the magnitude of the process. According to Dr. Merlinger, in real life "...a serious flaw in the imagined future of oncology is its underestimation of tumor heterogeneity."

The authors logically concluded that a single needle biopsy of a cancer mass will tell you little or nothing about the genetics of any other masses within the body, and that this would make personalized treatments very difficult. But the implications of this are worse.

The use of specifically targeted cancer therapies (called kinase inhibitors)--new drugs that have been designed to attack a specific growth pathway in the cancer cell--has been the holy grail of oncology research for some time. But much of original hype and promise about this revolutionary approach has not been realized. Ironically, part of the problem is that the very specificity that was desired was too much of a good thing.

Even if you could wave a magic wand and obtain all the genetic information of all cancer cells, there is still not that much you can do about it. The increased specificity of kinase inhibitors limits their damage to non-cancerous cells (fewer toxic side effects), but also decreases their ability to kill mutated cells from the same tumor.

This may explain why it is not uncommon to see impressive responses at the beginning of treatment, with profound tumor shrinkage. However, the mutated cells--which are either part of the original tumor or form later on--will eventually thrive in the space left behind by the original tumor. When the cancer returns it is much less treatable.

This heterogeneity points out one of the big obstacles in oncology research--the lack of a good animal model. Certain mice are bred to have no immune system. This enables scientists to implant cultured human cancer cells under their skin, and the cells will grow into a tumor.

But the implanted cells are much more homogeneous and more susceptible to attack by the new drug. When treated with the experimental drug, the tumor will often disappear entirely. When applied to real life, things are not so simple. This tumor heterogeneity will be a major barrier to overcome to take this approach to the next level.

It is unlikely that we will see groundbreaking advances in oncology comparable to what happened with other deadly diseases, such as AIDS and hepatitis C, which can now be effectively controlled or cured. Virtually all chemotherapy regimens use one or more drugs that were first used in the 1960s. Reliance on 50 year old drugs as the first line of defense is a good indicator of how difficult the problem really is. There is a long way to go.

Sam (The Sham) Waksal Gets A Really Bad Idea

By Jonathan (Josh) Bloom, Ph.D.
March 9, 2012

Medical Progress Today

I had to read something twice yesterday to convince myself that someone didn't spike my Cap'n Crunch with LSD. Turns out they didn't. Which is for the most part good, except that I'm still having trouble explaining what I saw.

Sam Waksal, the founder of ImClone, probably best remembered for the insider trading scandal of 2002, yesterday published an opinion piece in The New York Times, entitled "Pay Only for Drugs That Help You," in which he suggested an "interesting" way of making drug companies more innovative.

While his idea certainly gets high marks for creativity and novelty, it also ranks near the top of the "You Must Be Kidding Me" scale.

Citing the $2.6 trillion that the US spends on health care with little to show for it (which I don't buy at all) Waksal proposes that individuals and insurance companies should only be held responsible for paying for drugs that "work" for them. Waksal calls this a "pay-for-response model."

He cites as an examples cancer drugs, which would have to meet criteria established by the FDA for any given patient, or the company would not be paid for the drug. He also applies this standard to new drugs for hepatitis C, which would have to cure the patient for the companies to be paid.

While the concept behind this idea might be intruiging to some, to me it is simply insane. Here are a few reasons why.

First, response to cancer therapy is not a simple measurement. It involves multiple factors, including tumor growth, or shrinkage, increased survival time, increased time without disease progression (these two are not the same), and ancillary issues, such as pain relief, weight gain and time in the hospital. Good luck trying to come up with a set of standards at all, and even better good luck trying to apply them to individual patients.

If a tumor shrinks by 30% instead of a theoretically required 35%, is there really a difference? What do you do then? Yet, some numbers will need to be used to make this call. What will you do if the tumor grows, but the patient survives a few months longer than expected. One could spend hours arguing about whether the response of one patient meets criteria to determine if something "works." Now imagine trying to do this on a national scale. Nightmare.

And if Waksal thinks that this will spur innovation by drug companies, he couldn't be more wrong. Things are bad enough right now. It is impossible to determine how well a drug really works until it is marketed and widely taken. But if you add this subjective measurement to the mix why on earth would a company spend $1.3 billion and 15 years to get something approved, and still not have the slightest idea if they'll get compensated for their efforts.

No- this would not spur innovation. It would spur the end of drug discovery entirely.

And why apply this concept solely to drugs? If a neurosurgeon removes a herniated disk from my neck and I still experience some pain later on, should he be paid? If my investment adviser fails to meet my expectations for my portfolio, do I get me fees back? If I go to a lousy Broadway show or the Yankees lose, do I get my money back?

Aside from being medically counterproductive, this concept is illogical at its roots. There are no guarantees in life, especially in the medical world. You pays your money, you takes your chances.

4-Methylimidazole Warning # 407

By Jonathan (Josh) Bloom, Ph.D.
March 5, 2012

Medical Progress Today

The folks at Center for Science in the Public Interest (CSPI) have apparently run out of poisons to scare us with because they are now recycling some oldies. Their scare du jour is called 4-methylimidazole (4-MEI). Yawn.

Old, like in 1951--the earliest paper I could find in which the compound was studied for toxicity in rats. The rats are most likely no longer alive, but it wasn't because of the 4-MEI. Nothing happened to them during the experiment.

In fact when the authors tried to find the minimum amount of 4-MEI required to show toxicity, it was estimated to be 5 grams per day per rat, a crazy high number. Applied to humans, that comes to 700 grams per day. To put this in perspective, this is weight of 3 boxes of Kraft macaroni and cheese before cooking. That's how much chemical you would have to eat. It's not clear whether that much mac and cheese would also kill you.

Having worked (and played) with chemicals for 30 years, I developed a pretty good idea which ones are bad (e.g. getting one drop on the back of your lab glove and dying) and ones that you could pretty much bake into a creme brûlée without anyone noticing much of a difference. 4-MEI is quite a bit closer to the latter.

Which isn't all that unexpected, since it is one of components of caramel coloring, which has been used in a variety of food and drinks since before the Civil War. It gives color and flavor to soda, potato chips, beer, ice cream and whiskey to name a few. Doesn't really sound like much of a poison.

So if they can't convince people that a can of Pepsi is going to make you take an immediate dirt nap, the old cancer scam is a fine substitute. Cancer is really scary. And we all know from watching TV celebrities that we are just swimming in

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4-Methylimidazole Warning # 407

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a vast ocean of carcinogens as a result of living in modern times. That explains why cancer rates are dropping every year! Wait a minute. No, it doesn't.

Here's how most things get labeled carcinogens: Rats or mice get fed ridiculous amounts of a chemical for their lifetime, and are then examined for tumors. Some of them get tumors. What this has to do with human health in not obvious. Does this chemical really cause cancer? The answer is "who knows?" These experiments have so little to do with mimicking a real life situation that they are essentially worthless.

This is not to say that there aren't real carcinogenic chemicals. Of course there are. All chemists have worked with them at one time or another and you have to be really careful. But this ain't one of them. The "evidence" of human carcinogenicity of 4-MEI is nonexistent. Yet that doesn't stop CSPI issuing the headline "Lab Tests Find Carcinogen in Regular and Diet Coke and Pepsi" today. Please.

While these guys are busy measuring barely-detectable amounts of chemicals in this and that, they are doing us all a disservice by taking attention from real risks, like smoking, drunk driving, obesity and The Real Housewives of New Jersey. Give us a break, guys. We have enough to worry about.

Drug Reps: The Perfect Rx For Bad Doctors

By Jonathan (Josh) Bloom, Ph.D.
March 2, 2012

Medical Progress Today

I have written in the past that, although pharmaceutical sales reps are usually considered to be one step above head lice on the food chain of life, they actually perform quite a valuable service in educating physicians, many of whom have absolutely no time to time to keep up with the literature on new drugs.

Little surprises me any more, but that changed last week--in a big way.

A friend of mine who has been going through some rough times decided to give drug therapy a chance. He was put on one of the standard SSRI antidepressants by a very expensive New York psychopharmacologist.

Within two weeks, he was feeling nauseated much of the time, and had lost a lot of weight, so he called me for advice. It didn't take House to figure out this one. Nausea is one of the very common symptoms of SSRI use. Fortunately, it can be controlled with Zofran, an anti-emetic drug originally developed to treat chemotherapy-induced nausea and vomiting (CINV). It did this so well that oncologists maintain that it revolutionized the field, enabling patients to complete their chemo, even with the most emetogenic drugs, such as cisplatin. And to do so with far more comfort than before.

Zofran (generic name ondansetron), one of the most important pharmaceutical discoveries in a generation, is now also used to treat nausea and vomiting caused by general anesthesia, morphine, pregnancy, viral gastroenteritis and SSRIs.

Being in the pharmaceutical universe for my entire career, it's not unusual that I sometimes know more about certain drugs than the doctor I'm visiting. They are generally pleased to learn something new. But this is not my job.

In the absence of any Continuing Medical Education requirement for physicians about new drugs, it becomes the job of the reps to inform physicians about new products.

> "I told my friend to get another doctor, and this time to check whether there was actually a license behind the desk."

So, it took no special wisdom for me to suggest that he call his doctor and see if he would call in a script for some. Which was a perfectly fine plan until he called me back, saying that the doctor had never heard of it.

After removing my jaw from my desk, I tried to come up with any explanation of why a $400 per hour New York psychopharmacologist had never heard of a drug that had not only been on the market since 1991, but had transformed the fields of oncology, obstetrics and pediatric care.

The best I could do was "he was having a bad day." But I don't really believe that.

This is a valuable service, and perhaps it is time that this side of the story is considered. Although this system certainly has its flaws and the potential for abuse, on the whole, I believe it is far more useful than harmful.

I told my friend to get another doctor, and this time to check whether there was actually a license behind the desk. I feel badly for the other patients. Unless there are shrunken heads on the wall, or bottles of chloroform lying around, they may not know that they are seeing someone with a frighteningly limited knowledge of modern pharmaceuticals.

Hippocrates and Hypocrites

By Jonathan (Josh) Bloom, Ph.D.
February 27, 2012

Medical Progress Today

It's no secret that the world of practicing medicine has undergone a radical change. For years, we have been reading about physicians, fed up with fighting with insurance companies and financially hurting from obscene malpractice rates, static (or decreasing) reimbursement rates have become deeply disillusioned with medicine and are leaving the profession.

And unless something is done within the next month, an automatic 27 percent cut in Medicare reimbursement to doctors will make what's happened so far look like a picnic on a sunny day, leaving our healthcare system in a shambles--especially for seniors.

While about 95% of physicians now accept Medicare patients, if the 27 percent cut is applied, doctors will lose money by treating them. In fact--a 2011 survey shows that should this happen, 31% of doctors will stop accepting new Medicare patients, and another 45 percent said that they were unsure. More than half said they would reduce the numbers of appointments for current Medicare patients. If you're over 62, you are going to have quite a problem on your hands.

So, what are the administration and Congress doing to help? How about giving doctors a nice slap in the face.

In the interest of "transparency," Congress wants to expose any possible conflicts of interest between doctors and drug companies. Matters as trivial as having pharmaceutical sales reps provide bagels for a doctor's office are scrutinized and must be reported. And all grants to physicians, whether for collaborations or consultations with drugs companies must also be reported.

Much of this comes from a report in last month's New York Times that concluded that doctors who took money or gifts from drug companies practiced medicine differently (not worse) than those who didn't. And that sales reps who buy lunch for the office accomplish little more encouraging doctors to try new, more expensive drugs on their patients. In other words, doctors are on the take.

Left unstated is the fact that new drugs very often have substantial advantages over old ones. Doctors, lacking the time to keep current with the literature, may only learn about these new products by meeting with pharmaceutical sales reps. And that payments to doctors for collaboration or consultation is nothing more than a bribe, not a way to advance medicine.

The fact that Congress and the Obama administration are doing this in the interest of transparency is especially galling. As if the disclosure of physicians being compensated--whether for collaborating with or advising for drug companies, or getting a free dinner --is the remedy our care system needs.

Well, it's not. And if the current trend continues there will eventually be a critical shortage of doctors that will hurt all of us. Well, maybe not all of us.

In the interest of transparency, Congress happens to have its own medical plan that the rest of us would die for (or not die at all). While we are waiting days or weeks for an appointment or traveling hundreds of miles to see a doctor, they will not.

And to avoid conflicts of interest, perhaps Congress will explain why they, their families, and their aides have been getting rich (legally) by insider stock trading -- based on pending legislation on which they will vote, having a direct and predictable impact on the performance of companies they have already invested in. Unfortunately, they cannot be tossed in jail to keep company with any of us who might have tried this.

Congress is demanding transparency and accountability from others, while providing none of it themselves. They focus on minutiae and pad their pockets while our medical profession is in peril, and theirs is not.

I sure hope my own doctor manages to stick it out for a while. I may need him. The hypocrisy of our leaders is making me sick.

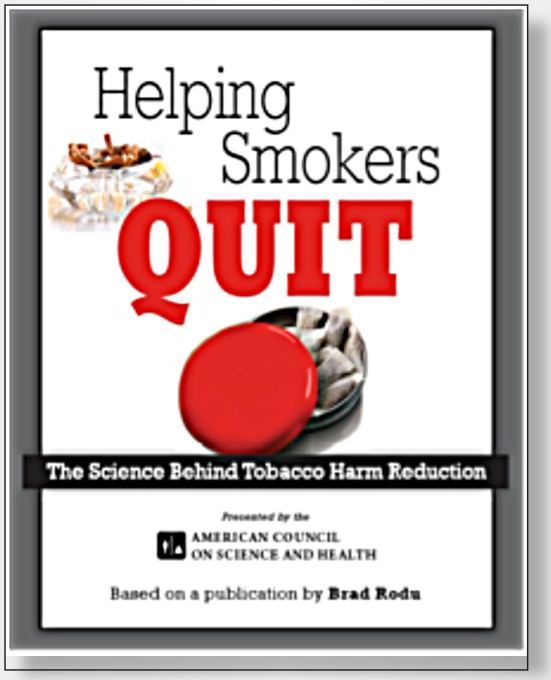
(Author's note: Congress did vote to postpone the Medicare reimbursement cut, but only for the balance of 2012. After that, a 30 percent cut will take effect.)

"A 2011 survey shows that should this happen, 31% of doctors will stop accepting new Medicare patients, and another 45 percent said that they were unsure. More than half said they would reduce the numbers of appointments for current Medicare patients."

New ACSH Publication

Helping Smokers Quit: The Science Behind Tobacco Harm Reduction

February 14, 2012



The American Council on Science and Health (ACSH) was among the first organizations in the United States to formally endorse tobacco harm reduction (THR). ACSH bases its position on a comprehensive review of the existing scientific and medical literature, which shows that smokeless tobacco is at least 98 percent safer than smoking cigarettes and can serve as an effective cessation aid.

This publication summarizes the major findings of the most recent comprehensive overview of the scientific literature on THR, undertaken by Dr. Brad Rodu, professor of medicine and endowed chair in tobacco harm reduction at the University of Louisville. It is ACSH's belief that THR can significantly reduce the toll of addiction to cigarettes that remains a major public health concern. It is the intention of this publication to increase the number of people who are aware of THR as a beneficial alternative to smoking.

Purchase your own copy on Amazon.com

How Health Regulators Are Killing American Smokers

By Gilbert Ross, M.D.
February 17, 2012

Cigarettes are by far the gravest threat to America's public health — a killer far worse than obesity, contagious diseases, and cancers of the colon, prostate and breast combined. Forty-six million Americans still smoke, despite all the warnings and taxes. That's about one-fifth of us — way down from its peak in the 1960s, but stubbornly resisting further declines. About 450,000 Americans die needlessly each year from inhaling the toxins and carcinogens in smoke.

Now consider that science actually has the means to dramatically reduce this public health catastrophe: tobacco harm reduction. As applied in other areas of public health, the benefits of harm reduction are well known: the idea is to reduce the health consequences of a substance or behavior without demanding complete abstinence from it. Distributing condoms to people who are known to engage in risky sexual activity is one example; providing IV drug addicts with sterile needles is another. By contrast, the "abstinence only" approach demands that the addict completely renounce their substance of abuse. It's an all-or-nothing attitude that, unfortunately, fails to help a lot of the people who need it most.

Although about two-thirds of smokers would like to quit, and one-third actually try to quit each year, fewer than five percent succeed. For those 450,000 American smokers who die each year, clearly, an abstinence only approach has not worked. Nicotine addiction is extremely strong. Yet, in a perversion of science-based public health policy, the truth about effective methods to help more smokers quit has been ignored, indeed suppressed, by our public health authorities who continually

deny the mountain of epidemiological evidence pointing to the benefits of tobacco harm reduction.

Tobacco harm reduction advocates the use of reduced-risk nicotine products, which allows addicted smokers to curtail their smoking without forcing them to eliminate nicotine altogether — an extraordinarily difficult task. Nicotine is the major reason inveterate smokers fail to quit: the craving for nicotine is as strong as that for heroin and cocaine. Yet the spectrum of smoking-related disease is not caused by nicotine, but by the products of tobacco combustion inhaled many times a day for decades. Nicotine is addictive, but it is not itself harmful.

That explains why tobacco harm reduction saves lives. Its goal is to reduce the devastating health risks of tobacco. The success of this policy in Sweden over the past four decades is widely accepted — but not among America's tunnel-visioned health regulators. Thanks to snus, moist smokeless tobacco in small pouches, Swedish men have the lowest smoking rate and the lowest rate of smoking-related disease and death in Europe.

Yet our public-health officialdom ignores or denies these data, adhering to the mantra "There is no safe alternative to smoking." They ignore or deny the results demonstrating that snus-type smokeless tobacco is about 99% less harmful than cigarettes. On the other hand, studies of the traditional cessation methods show that these products — patches, gum, inhalers, medications — simply do not work. But that inconvenient fact has not deterred our officialdom from insisting that smokers stick to these useless products. Their abstinence-only attitude refuses to acknowledge the documented benefits of smokeless tobacco as a cessation aid, not to mention the apparent benefits of newer products, such as dissolvable tobacco and "clean nicotine" delivery systems that include electronic cigarettes.

Worst of all, there is little hope in sight to remediate this tragic situation. The FDA's position is that the benefits of reduced risk products for harm reduction must be "proven" before they can be recommended to smokers in America. But here's the Catch-22: Only the tobacco industry has the requisite expertise and finances to perform the long-term, large-scale, super-expensive studies needed to prove the benefit of these products to the FDA's satisfaction. The tobacco industry is explicitly barred, however, from supplying the needed data.

Given the intolerable loss of life and health attributable to smoking, why are the skeptics at the FDA, the American Cancer Society and the CDC stonewalling America's smokers about harm reduction? I believe it's because those experts recall too well the tobacco industry's reprehensible behavior during the last century, and simply do not trust anything that the industry proposes.

But who pays for this failure to enter the 21st century and accept reality? Not the experts. Not the tobacco companies. No, the victims are the 45 million addicted smokers, and the families of those who couldn't quit before cancer or heart disease struck. The time is long past when that approach should have evolved, to help smokers get the help they need to quit the death-dealing cigarette.

Boy, Are We In Trouble

By Jonathan (Josh) Bloom, Ph.D.
February 14, 2012

Medical Progress Today

Having spent a fair amount of time lately writing and talking about two particularly critical medical issues, my only viable current solution is to hide under the bed. But I'm not sure that's there is room for me and the dust, so I'll just vent here.

We are headed for big trouble in two areas of our health care. I don't know which is worse.

First, in the absence of a sudden congressional agreement on a pending bill, the Medicare reimbursement for doctors will automatically drop by 27% by at the end of this month. It will be a very bad time to be 65.

A 2011 survey conducted by the Medical Group Management Association polled over 93,000 doctors about how they handle Medicare patients-- now and if the cut goes through. Right now, over 95% of the respondents accept Medicare patients. But if Congress does nothing (something they excel at), the numbers change in a big way.

In that event, 31 percent of the respondents said that they would stop accepting new Medicare patients, and another 45 percent said they were uncertain. Let's say that the undecideds split evenly when it is time to decide. This will mean that more than half of the doctors in the US will stop seeing people, simply because they happened to turn 65.

Thirty-five percent of the respondents said that would reduce the number of appointments for existing patients, while 51 percent said they would do so for new patients. Nine percent said they would stop treating existing patients entirely.

This ain't good. And it's already happening. A number of recent stories have looked at what seniors face even before the end of the month. One story in particular was particularly awful. A senior woman in Connecticut spent the better part of a day just trying to find a doctor that would see her. The first four offices she called said they were no longer accepting Medicare patients, and the rate cut hasn't even taken place. Pretty horrifying.

Another big mess is the continuing, or maybe growing number of essential, generic drugs that are unavailable because of shortages. Last August I wrote an op-ed in The New York Post about people suffering and dying because their doctors or hospitals were unable to get staples such as epinephrine, morphine, antibiotics, cancer drugs and general anesthetics. There are about 250 drugs in short supply, and that number has been growing every year.

> "In the absence of a sudden congressional agreement on a pending bill, the Medicare reimbursement for doctors will automatically drop by 27% by at the end of this month. It will be a very bad time to be 65."

The only "remedy" announced since then was an executive order from President Obama. He directed the FDA to: 1) collect information about impending shortages and work with manufacturers to at least be aware of the shortages; 2) speed up inspections of manufacturing facilities (pretty much impossible, since they are drastically short staffed) and 3) work with the Justice Department to identify instances of collusion and price gouging. The FDA has no power to force any company to make anything, and all the inspections and criminal prosecution in the world won't change this.

So, rather than do anything useful, the administration seemed to be more interested in punishing price gougers, who were raising prices on drugs in short supply by absurd amounts, since desperate hospitals had no choice but to buy them. Hardly an ethical business practice, but perhaps we should worry about the shortages first and market abuses later. And one could argue that the required advance notification of impending shortages will make the problem worse by tipping off unscrupulous buyers to hoard drugs that will soon become unavailable.

The answer to this problem is not at all obvious. Many very smart people have been discussing this and there is no simple solution. Although a good place to start might be to lift the price controls on generics that started the problem. The shortages consist mostly of simple generics where there is little or no profit to be made given price constraints. Seems pretty simple, no? But that would involve doing something to help drug companies-- a political no-no if ever there were one.

Pay attention to this. It will only get worse. The hatred for the pharmaceutical industry is so strong that it is now impossible to get even necessary things done, should there be any hint that a profit will be made. Perhaps some of our political leaders will learn the hard way about how the perpetual demonization of an industry will come back to haunt them. Maybe when people with heart attacks start showing up in the ER only to find that they are short on epinephrine, saline and morphine will they belatedly realize that government policies, made in the name of affordable medicine or simply for political expedience, weren't such a great idea after all.

Should Patents On Pharmaceuticals Be Extended To Encourage Innovation?

YES: INNOVATION DEMANDS IT

By Jonathan (Josh) Bloom, Ph.D.
January 23, 2012

THE WALL STREET JOURNAL.

The American pharmaceutical industry is seriously ill. And extended patent protection is just the medicine the drug companies need.

Pharmaceutical companies have long been demonized by many politicians and others as heartless behemoths that place profit ahead of people's well-being.

> "Drug makers are now required to conduct more studies with many more subjects. That adds to costs and stretches out development times."

But that perception couldn't be more wrong. The profits these companies make on blockbuster medications support the research that produces such breakthroughs. And the scientists working in the labs are fervently committed to finding useful new medicines.

Unfortunately, there are far fewer of those scientists at work than there were 10 years ago, and their companies are in trouble.

What's the problem? A confluence of events in recent years has made drug discovery more difficult, expensive and time consuming. Most important, it has become less profitable, largely because longer development times mean companies have less time left under patents to exclusively market their discoveries. Now, the industry faces a financial crisis because of the recent or imminent expiration of the patents on many of its most profitable drugs.

Without extended patent protection for new discoveries, the industry won't be able to fund the current level of research. And the consequences are profound: decreased innovation, fewer new drugs and more job losses.

Ugly Numbers

Next time you hear about a drug making billions of dollars for its maker, consider this: Currently, bringing one new drug to market takes roughly 14 years, at a cost of about $1.3 billion. For every drug that makes it to market, more than 50 other research programs fail. After all that, only two of every 10 newly approved drugs will be profitable. Those profits must fund not only all the research programs that failed, but also all the drugs that are launched but lose money.

When the industry was producing a steady stream of blockbuster drugs, as it did beginning in the 1990s (for example, all the AIDS drugs), the math worked in its favor. But in recent years the numbers have turned against the drug industry, for several reasons.

For one, the Food and Drug Administration has become more risk-averse in the wake of the 2004 Vioxx debacle. Drug makers are now required to conduct more studies with many more subjects. That adds to costs and stretches out development times. And every year spent in clinical trials equals one year of lost patent coverage.

In 1968, when development time was much shorter than today, most drugs had an effective patent life of about 17 years. Now companies usually have only about 11 years of market exclusivity for their drugs. And this number is expected to continue dropping as development times grow even longer—approaching a point where the costs and risks of development outweigh the rewards and research will stop.

Many of the diseases addressed in the 1990s were simply easier to tackle. Since then, despite increased research spending, fewer breakthrough drugs have been discovered. Difficult conditions such as cancer, Alzheimer's, Parkinson's and obesity remain problematic.

Amid all these challenges, the drug industry is losing its financial cushion as patents from the 1990s expire. Since 2006, brand drugs have lost an estimated $60 billion in sales because of patent expirations; by 2015, this figure is projected to rise to $160 billion. This is the so-called patent cliff.

It shouldn't be surprising, then, that the industry is showing signs of stress. The share prices of the major drug makers have fallen sharply in the past decade, and weakened companies have succumbed to mergers and acquisitions, causing the elimination of 300,000 jobs during this time.

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Should Patents On Pharmaceuticals Be Extended To Encourage Innovation? Yes: Innovation Demands It

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Stretch Some, Cut Others

Extension of patent life for the most innovative drugs would, at the very least, postpone the rush toward the patent cliff, providing drug companies with extra time to discover the next cycle of new, innovative therapies.

With U.S.-based drug companies scaling back their research, there will be fewer discoveries to fill the gap and keep new treatments coming to market. Academic researchers are very good at studying the basic biology of a disease, but this is just the very beginning of the discovery process. The lion's share of the work—progressing from basic biology to an actual drug—requires the expertise and resources that academic and government labs simply don't have.Of course, longer patents would mean that important drugs would remain relatively expensive for a longer time. But the expense of new drugs is preferable to not having them at all. The fact that drug companies thrived in the past without patent protection is irrelevant. Companies didn't face the regulatory and competitive environment of today. For example, generic competition was minimal until the 1980s.

Remember that manufacturers of generic drugs contribute nothing to innovation. Yet they take up to 90% of sales away from the comparable brand-name drugs whose makers risked the time and money to bring breakthrough treatments to market.

There are some drugs that deserve less patent protection. These are the so-called line extensions—where companies simply tweak existing drugs enough to earn a new patent. Virtually identical to the original compound, these provide little real innovation. When companies are under economic stress, line extensions may become an attractive way to keep revenue flowing, drawing resources away from innovative, more important work.

To discourage that and to keep drug companies focused instead on innovative treatments, patents for line extensions should be shortened, perhaps by three years or so, while patents for high-risk, first-in-class drugs and those that address unmet medical needs should be extended significantly—five more years could be a starting point for discussion. (Most drugs now get 20 years of protection from the time a patent application is filed, which is effectively about 11 years after accounting for development time.)

One alternative that has been suggested is that in order to gain FDA approval, new drugs should have to demonstrate superiority to existing ones. This would be unrealistic because that standard could hardly ever be met in clinical trials—in nearly all cases you can't tell the real differences between two drugs until they are in the marketplace and being taken by millions of people.

A well-planned extension of patent protection, especially for innovative drugs, is both reasonable and necessary to keep what is left of the American pharmaceutical industry healthy enough to continue its crucial work. In the absence of a remedial measure like patent-life extension, the industry will continue its decline, resulting in incalculable losses to the U.S. economy and poorer medical care for its citizens. This would be a national disgrace.

Read the entire debate: http://online.wsj.com/article/SB10001424052970204542404577156993191655000.html

"Extension of patent life for the most innovative drugs would, at the very least, postpone the rush toward the patent cliff, providing drug companies with extra time to discover the next cycle of new, innovative therapies."

Garbage In, Anti-Nuclear Propaganda Out: The 14,000 Death Fukushima Lie

By Jonathan (Josh) Bloom, Ph.D.
January 12, 2012

I've seen some bad studies in my day, and also some irresponsible headlines. But last week, a couple of antinuclear activists managed to do a superb job at both. The title itself was a giveaway: An Unexpected Mortality Increase in the United States Follows Arrival of the Radioactive Plume from Fukushima: Is There a Correlation?

Drs. Joseph Mangano and Janette Sherman, writing in the International Journal of Health Services, proposed that there were 14,000 "excess" deaths in the U.S. following the accident at the Fukushima Daiichi nuclear plant in Japan, due to the release of a plume of radioisotopes over 5000 miles away. This theory is preposterous on so many levels that I don't know where to start.

The "study" found that during the 14 weeks following the accident, death rates in 104 U.S. cities were about 2 percent higher than those for the 14 weeks before the accident, constituting about 3,300 "extra" deaths. Applied to the entire country, this number rose to 14,000. Right away this smelled fishy. But that didn't stop Mangano, as quoted in MedPage Today, from concluding that the finding is "a clarion call for more extensive research." No it's not—it's a clarion call for some common sense.

The only two (barely) conceivable ways that such a plume could kill anyone are cancer or radiation poisoning. Cancer can be ruled out immediately, since there is no way it could even begin to develop in such a short period of time, let alone kill anyone. Cancers take years, or even decades, to grow—not weeks. And, almost all of the radioactive material released was iodine-131, associated with thyroid cancer, which is one of the slowest growing and least deadly cancers.

Forbes.com

An explanation involving radiation poisoning is not quite as absurd, but almost. If you're wondering how enough radioactive material could arrive here and kill Americans within 3 months, you are not alone. And even if it did get here, some sort of geographical pattern of illness and death would logically be expected.

"An explanation involving radiation poisoning is not quite as absurd, but almost. If you're wondering how enough radioactive material could arrive here and kill Americans within 3 months, you are not alone."

Good luck finding it in this data.

For instance, in the 14 weeks following the accident, there were 82 "extra" deaths in New York and 336 in Philadelphia, compared to the same time period in 2010. At the same time, Los Angeles— which is 3000 miles closer to Japan—had 246, while in San Diego there were 137 fewer deaths. And if that doesn't make sense, consider Houston. Although the city had 484 "extra" deaths during this time, in the 14 weeks prior to the accident there were 1,649 fewer deaths (45%) than in 2010. Must have been a very healthy year there. Or some utterly meaningless data.

Upon closer examination of the data, things get worse. The authors—in their effort to support a crackpot theory— used data that is essentially useless. What data was available came from a very small number of samples, and these showed very little radioactivity. For example, they analyzed a grand total of 67 milk samples and found measurable radioisotopes in just 15 of them. Likewise, in 153 samples of drinking water, only 36 had any radioactivity.

In trying to make a case against nuclear power, the authors have succeeded only in embarrassing themselves. They are asking us to believe that radiation released from a plant in Japan (where no one died) somehow traveled 5,000 miles across the Pacific Ocean to the U.S., where it haphazardly killed (or in some cases saved) thousands of Americans by a process that is utterly implausible—all by manipulation of dubious statistics. Nice job, guys.

I happen to believe that, given the available technology, nuclear power is among the safest, cleanest and most practical options we have. Other people have different yet reasonable opinions on this issue, which is fine. However, when garbage like this gets into the scientific literature, some people will actually believe it; the discussion then becomes contaminated with false information, and a reasonable conversation about nuclear power becomes even more difficult to come by. Propaganda that poses as science is irresponsible. And as for the editors of the International Journal of Health Services: Shame on you.

Preposterous Propositions

By Josh Bloom
January 5, 2012

Medical Progress Today

When I opened my Christmas gifts last month, I came across one that was quite puzzling. It was something in a plain cardboard box with the following on the label:

WARNING: This product contains chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.

This got me wondering why my mother would get me a nuclear warhead as a gift. After all, I've been a pretty good son, and I don't remember asking for one. Then again, the package was too light, thus discrediting my otherwise plausible guess. So, what could be in there?

A bird feeder. A clear plastic thing with two holes in it.

Which got me thinking of all the ways that a bird feeder could harm me. Since it was too big to swallow, too small to stick my head in it, and came from California, it had to have something to do with good old Proposition 65, passed in 1986 to protect drinking water from toxic and carcinogenic chemicals. And it was--the warning was from Proposition 65, word for word.

What this has to do with bird feeders isn't immediately obvious.

So I looked up the chemicals covered by Prop. 65. There are about 500 of them. But no bird feeders.

But as I went through the list some of the things I did find surprised me quite a bit. For instance, all of them were classified as either causing cancer or having reproductive toxicity. Pretty scary.

There were many industrial chemicals in there, but also very common substances. For example, Valium is on the list. But let's say that you are tortured by an obsessive fear of getting cancer and fill a scrip from your doctor, isn't the label going to really screw with your head?

Likewise, if you have cancer and your chemotherapy includes Mitomycin C (on the list as a carcinogen), doesn't this send a mixed message?

Other carcinogens include pyridine (in coffee), orange oil and wood dust. Which suggests, at the very least, that one should not drink coffee while doing carpentry that requires an orange oil finish.

Also in there were AZT, gasoline, tetracycline, Mevacor, aspirin, codeine, nickel, oral contraceptives, and Chinese style salted fish. Lots of things.

While this may be humorous, it probably isn't so funny to anyone trying to run a business in California. Think about it--if you can't sell a bird feeder without stamping a cancer warning on it, I cannot even imagine what other regulations one must follow just to accomplish anything out there. And this is not unique to California.

In a recent blog called "Rebuttal to the Wonky Liberal" , Bill Kovacs of the U.S. Chamber of Commerce notes the economic effects that this type of mentality has on real people trying to earn a living or employ others. Kovacs details the story of the head of a concrete plant in New Orleans, and how new EPA rules are driving this industry (and many others) out of the country. The commentary is profoundly sobering, and anyone who wonders why all of our jobs seem to be going to China should read this carefully.

Maybe we need a new federal agency--The Department of Homeland Sanity. Because there seems to be precious little of it remaining.

I'd like to continue, but it's time to feed the birds. Really.

MEDIA APPEARANCES & INTEVIEWS

June 29, 2012

Dr. Ross Talks Tobacco Harm Reduction On The Radio

Dr. Ross joined Kenneth Anderson for his radio series on "Addiction Treatments that Work," where they chatted about tobacco harm reduction strategies, including Swedish snus, electronic cigarettes, and smoking reduction.

June 21, 2012

Dr. Ross On Vicki Mckenna Show

ACSH's Dr. Ross appeared on the Vicki McKenna radio show (News/Talk 1130, Wisconsin) on June 21, to discuss mercury poisoning in America.

June 21, 2012

Dr. Ross on The Laura Ingraham Show

On June 21, ACSH's Dr. Gilbert Ross appeared on The Laura Ingraham Show , a radio talk show streamed on hundreds of stations nationwide. The topic of discussion was the effects of inadequate sleep on American workers — 30 percent of whom are not getting the recommended amount of 7 to 9 hours of shuteye per night.

Aside from work-related accidents and absenteeism, chronic sleep deprivation can also lead to an increased risk of adverse cardiovascular events, motor vehicular accidents, depression, and even weight gain.

May 31, 2012

Interview With Mike Murillo

On May 31, ACSH's Dr. Ross was interviewed by Mike Murillo from FM News New York (101.9 FM) on World No Tobacco Day and how electronic cigarettes are an excellent choice for quitting tobacco.

May 30, 2012

Dr. Ross on WOR-AM

Dr. Ross was a guest on The Joan Hamburg Show on WOR-AM Radio on May 30 where he discussed tobacco harm reduction.

MEDIA APPEARANCES & INTEVIEWS

May 18, 2012

Tobacco Harm Reduction In Williamsburg

On May 18, Dr. Ross headed to Williamsburg, VA, to participate in a conference called "Evidence-Based Science and Regulation of the Tobacco Industry." Dr. Ross was the moderator of two different panels, one titled "Tobacco Harm Reduction and Medical-Ethical Issues," and the other called "The Swedish Experience," which discussed the role Swedish snus has played in lowering the rate of smoking-related diseases in that country.Dr. Ross to speak at AAAS

February 17, 2012

AAAS Conference in Vancouver

ACSH's Dr. Gilbert Ross was off to Vancouver, on February 18, where he spoke at a meeting of the American Association for the Advancement of Science (AAAS). He discussed the importance of using tobacco harm reduction methods to save smokers' lives. By encouraging smokers to switch from cigarettes to much less harmful sources of nicotine, such as certain forms of smokeless tobacco or electronic cigarettes, we can help greatly reduce the over 400,000 tobacco-related deaths that occur each year in the U.S.

January 28, 2012

NBC Nightly New With Lester Holt

On January 28, Dr. Ross appeared on the NBC Nightly News with Lester Holt to discuss social group mass purchasing of healthcare at a discount.

January 17, 2012

Dr. Allan Felsot Represents ACSH on Capitol Hill

On Tuesday, January 17, the American Council on Science and Health (ACSH) hosted a Capitol Hill briefing on the role pesticides play in protecting our food supply and public health. The event's speaker, Dr. Allan Felsot, Professor of Entomology and Environmental Toxicology at Washington State University, addressed "Feeding the World: Why Pesticides are a Critical Part of the Solution."

January 18, 2012

Dr. Felsot on pesticides, in DC and on TV

Dr. Felsot was also interviewed by E&E TV, January 18, where he discussed the role of pesticides in allowing us to supply the world's population with food and keep people healthy, countering claims that pesticides lead to dangerous toxicity in our foods. The interview coincided with Dr. Felsot's Capitol Hill briefing on "Pesticides and Health: Myths vs. Realities," the paper he authored for ACSH.

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