The Voice of the American Council on Science and Health

A Sampling of ACSH's Press and Internet Media Coverage July 2012 – December 2012

MEDIA UPDATE

OFF LABEL ADVICE FOR DOCTORS: THE APPEALS COURT IS DEAD ON

Josh Bloom, Ph.D.
December 5, 2012

Medical Progress Today

Off-label drugs — those used for indications other than what the drug was originally approved for — have been used for many years. Most of us have probably benefited from this practice, but despite this, it has been illegal for a pharmaceutical sales rep to even mention a possible off-label use of any drug to doctors.

That changed Monday, when the Court of Appeals for the Second Circuit in Manhattan curtailed the FDA's authority to limit what sales reps are allowed to say to doctors about their company's drugs, throwing out the conviction of a sales rep who was found guilty of selling a narcolepsy drug for off-label indications. The court's argument was based on First Amendment rights, and although I don't really know or care about the constitutionality of this. I just know a good idea when I see one.

I'm sure the anti-pharmaceutical activists will be howling about this one for quite some time. I can already see the headlines: "Big Pharma Money Buys Corrupts Courts" or "A Legal Win for Pharma; A Loss for Us."

And of course, there will also be countless analyses about how the First Amendment was not designed to permit sales reps to "illegally push" drugs that have not been approved for a particular use upon doctors and their patients. But until now, this was the law.

I never understood the law in the first place. It just doesn't make sense.

Once the FDA approves a drug for a particular use, a doctor can legally prescribe it for other indications. It happens all the time. It has been estimated than about 20 percent of all prescriptions are written for a non-approved indication. Given this, why should it be illegal to pass along information to doctors, letting them know about new treatments?

Well, it shouldn't. And there are good reasons for this.

First of all, drug reps are an important source of information for many doctors, who may not have the time to take courses or read medical journals. There are probably quite a few instances where the drug rep is theonly source of new drug information for a physician. The rep supplies information. It is then up to the physician to decide whether to use the drug or not.

Since off-label use is already a common practice, doctors have either decided to try this on their own, or have gotten some information from somewhere else. Where? A colleague on the golf course? A medical journal? From the patient himself? Who knows? Why not a sales rep? If you believe that they simply lie about everything to meet their quotas (and I certainly don't), they can just as easily lie about the new approved drug that they are selling. I don't see much of a difference between the two, nor do I believe it is common.

As long as off-label information exists, why should it not be transmitted? It is the doctors who will determine what is best for their patients and they will decide what to do with the information that get. No one will force them to use anything they are not comfortable with.

Second, any off-label drug has already been approved for something else, meaning that it has already gone through an exhaustive safety review that was required for its approval in the first place (yes– it is imperfect, so don't bother reminding me about Vioxx).

So, the use of an approved drug for condition X is not likely to be any more

continued on page 3

contents

contributors

Dr. Elizabeth Whelan is the founder and president of the American Council on Science and Health.

Dr. Gilbert Ross is the executive director and medical director of the American Council on Science and Health.

Dr. Jonathan (Josh) Bloom is director of chemical and pharmaceutical sciences with the American Council on Science and Health.

Roya Heydari is a research intern at the American Council on Science and Health

Dr Ruth Kava is a senior fellow in nutrition of the American Council on Science and Health.

Lana Spivak is the director of public health of the American Council on Science and Health

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.

ACSH President: Elizabeth M. Whelan, SC.D., M.P.H. **Media Update Editor:** Cheryl Martin
1995 Broadway, 2nd Floor, New York, NY 10023–5860 – Tel: 212.362.7044 – Toll Free 866.905.2694 – Fax: 212.362.4919
www.acsh.org – acsh@acsh.org

Off Label Advice for Doctors- The Appeals Court is Dead On

continued from page 1

dangerous than using it for disease Y, since the FDA has already deemed it sufficiently safe to use in the first place. (Of course there are exceptions–no doctor wishing to hold onto his license will prescribe a cancer drug for a backache).

But that cancer drug may be very useful in treating noncancerous diseases, and this highlights some of the real benefits of off-label drug use–something most people are unaware of.

Certain chemotherapeutic agents are effective for treating autoimmune diseases, such as lupus, multiple sclerosis and rheumatoid arthritis–three god-awful diseases that may not respond to other therapies.

And there are many others. Singulair, originally approved for asthma is used off-label for chronic obstructive pulmonary disorder (COPD). Antidepressants are used to treat chronic neuropathic pain, as is Neurontin, originally an epilepsy drug. Seroquel, and anti-psychotic drug is used as an adjunct in treating depression.

The beta-blocker heart drug Inderal is also used for treating migraine headaches, stage fright and PTSD. And Zofran, which revolutionized cancer chemotherapy by significantly reducing nausea and vomiting is used off-label for treatment of hyperemesis gravidarum, a severe form of morning sickness, which put Kate Middleton in the hospital this week.

To me, the entire concept that providing information to doctors needs to be artificially constrained is based on the presumption that we need to be protected from greedy and dishonest drug reps and doctors. I don't buy it. Yes, I'm sure there are some bad apples out there (as there are in any profession), but on the whole I believe this decision will provide a substantial net benefit to patients.

What's new with Plan B, the "morning-after" pill?

Gilbert Ross, M.D.
December 28, 2012

examiner.com

Now that a full year has passed since the abortive attempt by the U.S. Food and Drug Administration's Commissioner, Dr. Margaret Hamburg, to make the "morning-after pill" available to anyone over-the-counter (OTC), what is the status of this plan?

The unfortunate answer is: nothing has changed since her boss, Health and Human Services Secretary Kathleen Sebelius, quashed the FDA's plan last December.

The FDA wanted to remove any Plan B age restrictions, based on research showing that access to the morning-after pill does not increase a woman's likelihood to have unprotected sex, and that this drug is safe for use by girls as young as 11. Two studies reported that, when provided with Plan B, girls ages 11 to 17 were able to understand the package directions, and demonstrated that they could use emergency contraception safely and appropriately without the help of a physician. In fact, Plan B is safer than many other current OTC medicines, such as aspirin and other painkillers. While an overdose of any of these medications can have dangerous consequences, it is actually impossible to overdose on the morning-after pill. And any theoretical risk is far outweighed by the risk of an unplanned pregnancy in girls and young women.

The alleged rationale for the unprecedented step by HHS was that young teenage girls were not qualified to decide if and when to take the emergency contraceptive pill, which can protect against pregnancy for up to 4 days after unprotected sex.

Many of us in public health felt that this was merely an excuse for Sebelius' boss — President Obama — to avoid another controversy involving reproductive policies in the face of a tough election battle then upcoming. After all, if a 15 year old is old enough to have sex — and many teens do act accordingly, whatever their parents and authorities wish to believe — then she should be deemed old enough to protect herself against such a major life event as teen pregnancy. Further, while not 100 percent risk-free — no drug is — the morning-after pill is close to it, and much safer than an unwanted pregnancy in a teenager.

Now, the election is over. Further, the new healthcare law, the Affordable Care Act ("Obamacare"), has been upheld. Seizing upon this new opportunity, a consortium of eleven professional medical, nursing and reproductive medical academic societies — far from forgetting about the issue — have expressed their own concerns about enhancing access to emergency contraception through an open letter to Secretary Sebelius, published on the website of the American Congress of Obstetricians and Gynecologists: as well as in several other specialty journals.

There are some who continue to oppose this approach, believing (falsely) that more access to birth control and emergency contraception will encourage earlier sexual activity and promiscuity. There is no evidence that this will occur, and plenty that it won't. These folks fail to take account of the tragic rate of unintended teen pregnancy and births in our country, the highest in the developed world.

Unless some major shift in our philosophy about teen sexual activity occurs — including more comprehensive sex education and information about birth control methods based on facts, not superstition or fears — as well as easier access to pregnancy prevention, the unacceptably high risk of future-destroying or abortion-inducing teen pregnancy will go on unabated. Hopefully, the president and his HHS Secretary will be more flexible on Plan B when the FDA tries to OK it again in the near future.

Better birth control, coming to a pharmacy near you

Gilbert Ross, M.D.
December 4, 2012

examiner.com

Teen pregnancy is a hot topic in the media and pop culture these days, as attested to by movies including "Juno" to "Teen Mom 2″ to "16 and Pregnant." Events of recent weeks may indicate this concern is finally cracking the shell around our public health leaders as well — better late than never.

It's an inconvenient — and sad — fact that our nation has the developed world's highest rate of teenage pregnancy and its handmaiden, abortion. It's a problem that Republicans, Democrats, health care workers and public health officials all agree needs to be more effectively addressed — and physicians' groups have just come out with a series of proposals to do just that.

A few days before Thanksgiving, the major society of obstetricians and gynecologists in the U.S. issued an advisory recommending that oral contraceptives be made available over the counter, meaning no prescription necessary. They did not specify any age limit or cutoff for this suggestion. The rationale for this advice is simple: The fewer obstacles in the path of girls and women vulnerable to unintended pregnancy (meaning any sexually active female) to getting effective protection, the better.

Some might object that young teenage girls should not be allowed to just go to the local drugstore and buy birth control pills, while some point out — correctly — that pills do not protect against sexually transmitted diseases as well as condoms do. Others argue that "the pill" may have side-effects warranting discussion with a trained healthcare professional.

However, pregnancy — especially unintended pregnancy in a youngster — has far higher health risks than the minuscule risk of oral contraceptives in most girls. As for requiring the intervention of a responsible adult, preferably a parent, in this transaction, the unfortunate fact is that teens have sex (and get pregnant) without parental supervision. Requiring parental acquiescence would likely have the unintended consequence for sexually active teens of keeping their activities hidden and the benefits of birth control pills so close, but so far away.

That recommendation would ordinarily be enough of a birth-control breakthrough for a year or two. But lo and behold, only a week later, right after Thanksgiving, another erudite medical group had an even more remarkable announcement. The American Academy of Pediatrics — the nation's leading pediatric group — advised doctors caring for girls of childbearing age to give them a prescription for emergency contraception — the "morning-after pill" — at the time of their annual check-up.

Yes, you heard me right: Without delving into their young patients' sexual proclivities, they are advised to just routinely give them the prescription to carry with them, "just in case." The "just -in-case" scenario would be after unprotected sex, or if a condom should break, or in the less-common instance of sexual assault.

The morning-after pill reduces the risk of pregnancy by a substantial amount, if taken up to three to four days after sex. In fact, the sooner the medication is taken after unprotected sex, the less likely that pregnancy will result. Right now, women aged 17 years and older can purchase OTC emergency contraceptives, while girls younger than 17 must obtain a prescription. The reasoning of the pediatric society was simply that reducing the time between sex and taking the contraceptive pill would prevent pregnancy more effectively, so why not just give the girl the script in advance?

Studies have shown that adolescents are more likely to use emergency contraception if it's prescribed in advance, and since many teens engage in unprotected sexual intercourse, that seems like a wise plan. Other indications for use include contraceptive failures (defective or slipped condoms, or missed or late doses of other contraceptives). Again, some concern about foregoing barrier (condom) protection if the morning after pill is at hand is warranted, given the exposure to STDs. On the other hand, the fear that any form of contraception promotes earlier or promiscuous sex has been shown to be unfounded, and studies have shown the contrary: Good sex education actually leads to less sexual adventurism.

While the science behind this is strong, it seems a bit hard to swallow for many, parents and clinicians alike. Whether this policy catches on remains to be seen.

We are not yet done with reproductive health news. That same group of ob-gyns at the American Congress of Obstetricians and Gynecologists published a study in their journal, Obstetrics and Gynecology, analyzing the effects of giving out long-acting reversible contraceptives at no cost to poorer urban girls. These products — IUDs and hormonal implants — significantly reduced the rate of teen birth and abortions among almost 10,000 teens and young women in inner city St. Louis. They found that abortion rates plummeted by over half among the women getting the intervention, and teen birth rates were reduced by 80 percent!

How should we put all this together? The American public health approach to teen sexuality and its predictable consequences has mostly involved pretending it doesn't exist, and that the perverse effects of such a blithely ignorant policy — teen pregnancy, abortion, and disruption of young lives — must be tolerated. These sad and expensive outcomes are more pervasive in those areas where sex education is lacking by custom or law. New efforts to reduce teenage pregnancy such as those described in this article should be welcomed as medical and social progress.

The New York Times on Drugs

Josh Bloom, Ph.D.
November 30, 2012

Medical Progress Today

It is hardly surprising that The New York Times comes out with an anti-pharmaceutical screed on a regular basis. I usually just ignore them, but Thursday's article in Business Day was so slanted and amateurish that I couldn't pass up the opportunity to call them out.

The headline itself was the worst offender: "Brand-Name Drug Prices Rise Sharply, Report Says."

I'm guessing that they hoped that their readers would simply read the headline, mentally file away yet another pharmaceutical industry crime against humanity (soaking the consumer even more), and move on to the sports section to read about the Jets (arguably another crime against humanity).

Because if anyone had bothered to read the whole article, what is really going on is staring you straight in the face. But first, let's talk about some of the more disingenuous aspects of the report.

The first sentence reads "The price of brand-name prescription medicines is rising far faster than the inflation rate, while the price of generic drugs has plummeted, creating the largest gap so far between the two, according to a report published Wednesday by the pharmacy benefits manager Express Scripts."

The increase in branded drugs is 13 percent over the past year, while the price of generics has fallen by 22 percent. These numbers are both misleading and meaningless.

The obvious conclusion from the headline is: Those awful drug companies are making out like bandits, while the "little guys"–the generic companies– are suffering. And the difference between the rate of inflation and brand name drug prices is bona fide proof of this. Sounds good, but in this case, the use of the inflation rate as a surrogate measure of pharmaceutical company "greediness" is not only utterly meaningless, but intentionally deceiving.

Buried in the middle of the article are two sentences which give the real reason for the price increases, and I have to give them some credit for at least mentioning it. The report cited the growth of specialty drugs, which treat diseases like cancer and multiple sclerosis, as a major reason for the increase in spending on branded drugs. Spending on specialty medicines increased nearly 23 percent during the first three quarters of 2012, compared with the same period in 2011.

The use of the inflation rate as a surrogate measure of pharmaceutical company "greediness" is not only utterly meaningless, but intentionally deceiving

New brand name drugs are nothing like they were 10 or 20 years ago. We are talking about a whole different animal, so drawing any conclusion from these data is impossible. You might as well use the price of pork bellies on the Chicago Mercantile Exchange. Here's why.

The well-known "patent cliff" and supposed "lack of innovation" have put pharmaceutical companies in bad shape. This has not only led to the ongoing deconstruction of US-based research, but also a radical shift in the type of research that is being done.

A major consequence of this trend is that pills are pretty much passé. Virtually the entire industry has rapidly re-focused on specialty drugs–very expensive and often individualized therapies (most are biologics) that are mostly new therapies for cancer and autoimmune disorders–the areas that people (and sometimes insurance companies) are willing to pay $100 thousand dollars per year for a new drug.

The Express Scripts report explains quite nicely what is really going on–almost all of the newly approved drugs since July 1 fall under the category of speciality drugs. And yes–they are very expensive.

This is why branded drugs are outpacing inflation (as if that has anything to do with anything)–not because we are seeing massive price hikes on older brand drugs.

The fact that this shift in drug research has led to the use of much more personalized, difficult to manufacture and expensive drugs is the real story. Blindly comparing meaningless inflation data to make a point is disingenuous and inaccurate. One would think that The Times would strive for higher standards than the junk they put out this week.

Tami-flu the Coop?

Josh Bloom, Ph.D.
November 27, 2012

Medical Progress Today

Roche has recently been taking considerable heat for not providing certain clinical data on Tamiflu (oseltamivir), its flu drug that has been on the market since 1999. During the 2009 H1N1 flu scare, hospitals, governments and many individuals were panic buying it, and some of them are not too happy about spending a load of money on something that doesn't work very well.

If taken within the first two days of coming down with the flu, Tamiflu seems to knock off about one day (7 days down to 6) of the illness. It may also have some effect in reducing symptoms, but this is not clear. It also has some fairly nasty side effects. Given all of this, I have always considered it to be a marginal drug at best.

And if it wasn't especially effective before, it is becoming even less so now. To understand why, one needs to know a little about how viruses work.

Viruses are obligate parasites– they can only replicate within the host cell that they infect. They have come up with some fiendishly clever ways to survive and prosper.

All viruses use more or less this same strategy to replicate: After the virus binds to a particular receptor on the surface of its host cell (in the case of flu, these are lung and nasal cells) it enters the cell and "hijacks" the normal reproductive machinery of the host cell, tricking it into making the DNA or RNA of the virus instead of that of the cell. Then, using enzymes that are contained in the virus, new viral particles are assembled within the cell and burst in large numbers, where they seek new host cells, spreading the infection.

If any of these steps is short circuited by the presence of a drug, replication will stop. These discreet steps are referred to as targets, and most antiviral drugs (HIV being the best example) work by inhibiting a specific viral target.

The discovery of Tamiflu, as flawed as it is, represents a nice example of one of the spiffier technologies used in drug discovery–computer assisted drug design (CADD). In this case, the technique was used to design molecules that could interfere with the function of one of flu's essential enzymes–neuramidase.

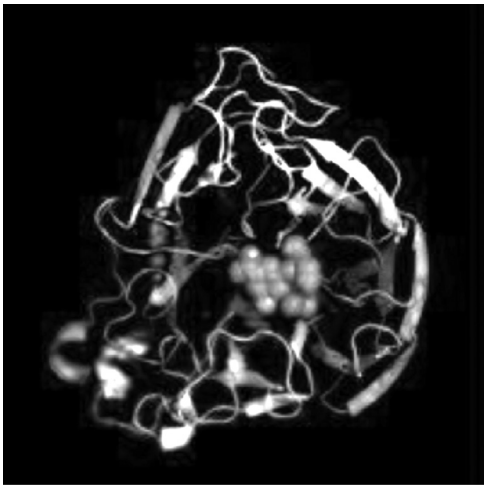
Oseltamivir binds to and inhibits neuramidase (the "N" in H1N1; the "H" stands for hemagglutinin, and good luck using that bad boy in Scrabble), thus preventing it from doing its job–acting like a pair of molecular scissors. After the flu virus is finished replicating within a cell, the new viruses burst through the host cell membrane, however, they are still stuck to the membrane until neuramidase comes along– cutting off the new flu virus particles allowing them up escape and infect other cells thus perpetuating the infection. If neuramidase doesn't function, the new viruses won't be released, and the infection can't spread.

Below is an example of CADD–oseltamivir (the mostly pink blob in the middle) bound to neuramidase (the colored ribbons). Using information derived from a technique called x-ray crystallography, chemists were able to visualize at the atomic level (in three dimensions) a set of imaginary molecules that would bind tightly and inhibit neuramidase. This led them to synthesize a series of molecules that did just that. One of these molecules was later named oseltamivir. And it worked–at least a little.

CADD has led to the discovery of many drugs–especially for HIV, and the science involved is elegant. But viruses don't much care for elegance–they simply want to replicate. And even the most scientifically rigorous and creative technology can be outdone by the tricks that the virus has up its sleeve. The most effective trick in its arsenal is mutation–a slight change in the structure of the virus or one of its components.

Most viruses mutate like crazy, and the best way to encourage them to do this is by exposing them to a single drug that inhibits the replication of the natural strain of the virus. Doing this promotes the growth of mutant strains that are less sensitive to the drug, allowing them to flourish in the absence of the natural strain–as perfect an example of evolution as you'll ever find.

This was never more clear than in 1987 when AZT, the first HIV inhibitor was approved for treatment of AIDS. It was a complete flop. Although AZT did inhibit the growth of HIV for a short period of time, the virus rapidly mutated rendering AZT essentially useless.



And this is exactly what is happening with Tamiflu.

According to a March 2012 paper in Lancet Infectious Diseases, in 2007/2008, a type A (H1N1) influenza virus was found to have developed resistance to Tamiflu. Within one year, this strain of flu had spread globally, such that virtually every strain of this virus around the world was resistant to this drug.

Whether other strains of flu will develop resistance of this magnitude remains to be seen, but Tamiflu is clearly an imperfect drug that may be of little or no use in the future.

Roll up your sleeve.

Mammograms: Not all they're cracked up to be?

Gilbert Ross, M.D.
November 25, 2012

examiner.com

For many years, women have been urged, cajoled, brow-beaten even, to be sure to get their annual mammogram. Starting shortly after puberty's arrival and breast development, young women get the word: the annual mammogram is necessary to save your life!

Now, a new study of the likely benefits of screening mammograms shows that the large majority of abnormalities found turn out to be non-threatening "lesions" that would be better left undetected and undisturbed. In other words, most biopsies and lumpectomies provoked by routine screening X-rays are cases of what epidemiologists call "overdiagnosis." This occurs when an indolent or benign growth is called "cancer," although it's not going to progress, invade, spread, or otherwise pose a serious health threat.

It is undeniable that breast cancer survival rates have declined in recent years, and many women and their doctors believe this is due to earlier detection from screening mammograms. The study authors maintain that this effect is largely due to improved treatments, both surgical and medical, rather than detection benefits. It is also true that women who have clinical abnormalities, such as a lump or skin or nipple changes, or have a strong family history of breast cancer, should not be skipping mammograms. But those are not "screening" tests, but rather diagnostic exams for clear indications. Screenings are done routinely every year or so without specific reason.

The conclusions and recommendations of the new study apply to those screening tests only. The authors state that if such mammograms actually saved lives by preventing progressive, life threatening cancers, than late-stage cancers would also be in decline at least as much as the early-stage tumors — and they are not.

The co-author of the study, Dr. H. Gilbert Welch, professor of epidemiology and biostatistics at the Dartmouth College School of Medicine, had this to say: "Our study raises serious questions about the value of screening mammography. It clarifies that the benefit of mortality reduction is probably smaller, and the harm of overdiagnosis probably larger, than has been previously recognized." These harms include repeated medical testing, sonograms, MRIs, biopsies and lumpectomies, and the often-needless anxiety of being told of a diagnosis of cancer, when in fact the abnormality detected is not life-threatening.

The study used data from the US Centers for Disease Control and Prevention survey and from the American Cancer Society database. These analyses showed that since the general recommendation for all women over 40 to have screening mammograms in the late 1970s, and 2008, early-stage breast cancers doubled in frequency, while late-stage cancers decreased only by only 8 percent. This led the authors to conclude that millions of women have been diagnosed with cancer for no benefit to their long-term health — indeed, to their detriment. A similar controversy, nearly a firestorm, occurred in 2009, when a federal advisory panel recommended that women under 40 were more likely to be harmed than benefitted by routine screening mammography, and that those 50 and over need only consider mammograms every other year, not annually.

The issue is not so cut-and-dried, however. Len Lichtenfeld, deputy chief medical officer of the American Cancer Society, said the society continues to recommend that women get annual mammograms starting at 40 years of age. "Many experts agree that there is some degree of overdiagnosis and overtreatment," Lichtenfeld commented, adding however that "you can't have a significant decline in mortality unless you're doing something right."

At the end of the day, the decision to have mammography routinely, and if so how often, is one that must be made by each woman, after thorough discussion of the likely benefits and risks with her physician, and maybe also with her family. But those who make women feel guilty about skipping the test, or who assert that mammograms are the best way to protect health, have less support now than they did before.

At the end of the day, the decision to have mammography routinely, and if so how often, is one that must be made by each woman, after thorough discussion of the likely benefits and risks with her physician.

Beta blockers are busted – what happens next?

Josh Bloom, Ph.D.
November 12, 2012

NewScientist

They have treated heart disease for 40 years, but it now seems that beta blockers don't work. What went wrong?

IT IS very rare for new evidence to question or even negate the utility of a well-established class of drugs. But after four decades as a standard therapy for heart disease and high blood pressure, it looks like this fate will befall beta blockers. Two major studies published within about a week of each other suggest that the drugs do not work for these conditions. This is a big surprise, with big implications.

The first beta blocker, Inderal, was launched in 1964 by Imperial Chemical Industries for treatment of angina. This drug has been hailed as one of great medical advances of the 20th century. Its inventor, James Black, was awarded the Nobel prize in medicine in 1988.

The 20 or so beta blockers now on the market are very widely used – almost 200 million prescriptions were written for them in the US in 2010. They are standard issue for most people with heart disease or high blood pressure. This may now change.

A large study published last month in The Journal of the American Medical Association found that beta blockers did not prolong the lives of patients – a revelation that must have left many cardiologists shaking their heads (JAMA, vol 308, p 1340).

The researchers followed almost 45,000 heart patients over three-and-a-half years and found that beta blockers did not reduce the risk of heart attacks, deaths from heart attacks, or stroke.

While this is not definitive, it's pretty damning, especially when another study – published just days earlier – found pretty much the same thing (Journal of the American Geriatrics Society, vol 60, p 1854).

The goal of this second study was to examine the effect of drug compliance on death rates in patients who had had heart attacks. About half of patients complied with their drug regimen. Unsurprisingly, these people were nearly 30 per cent less likely to die than those who did not comply.

This was to be expected, but there was one big surprise. While the result held for the standard classes of heart drugs – statins, anticoagulants and antihypertensives – it did not for beta blockers. Regardless of whether or not patients stuck to their regimen, their risk of dying was the same. Taken together with the JAMA study, it becomes very reasonable to question the benefit of beta blockers for treating these conditions.

To understand what is going on, consider how they work. Like many drugs, beta blockers target receptors embedded in the surface of cells. Receptors are "molecular switches" – when a specific molecule binds to them, they change shape and send a signal to the cell to perform a certain function. Beta blockers target beta receptors, which respond to the "fight or flight" hormones adrenalin and noradrenalin.

In humans, there are two principle types of beta-receptor – beta-1, primarily found in the heart, and beta-2, located at multiple sites, including the smooth-muscle cells of the bronchial tubes and in veins.

When adrenalin and noradrenalin bind to beta-1 receptors, they signal the heart to beat faster and pump harder. Binding to beta-2 receptors causes smooth muscle relaxation, especially in the airways, explaining why beta-2 activators are used as asthma drugs.

Beta blockers bind to both types of receptor, but do not activate the cellular response. This blocks adrenalin and noradrenalin from reaching their target and activating the response. By preventing the normal hormone-receptor interaction, the beta blockers slow the heart and cause it to pump less forcefully, lowering blood pressure.

The premise of beta-blocker therapy has been that giving the heart a rest will diminish the frequency of heart attacks. In the light of the two new studies, it is clearly time to question this.

Which raises the question: why has it taken so long to find out? It is worth noting at this point that this is not yet another case of a drug entering the market only to be withdrawn later because of lack of efficacy or even adverse reactions which could have been noticed with longer or larger trials. It is simply a new medical revelation. The authors of the JAMA paper provide a reasonable explanation of the conflict between their results and earlier studies.

The key word is "earlier". Most clinical trials on beta blockers took place before reperfusion therapy became standard treatment following heart attacks. Reperfusion involves opening the blocked artery by surgery or pharmaceuticals, and has been shown to significantly reduce damage to the heart.

Damaged hearts are more prone to fatal irregular beats, and beta blockers are useful in controlling this. But with the advent of reperfusion therapy, people who survived heart attacks suffered less cardiac damage, so the frequency of fatal arrhythmias was lower. Put simply, the beta blocker effect was significant before the advent of this improved treatment, but the beneficial effect has since disappeared.

Additionally, newer and better drugs such as anticoagulants, statins and antihypertensives are now routinely used in heart disease. These more effective therapies swamp any smaller benefit that the beta blockers might provide, minimizing any measurable effect.

What comes next is impossible to predict, but we may well be seeing a rare case of medical wisdom being overturned almost overnight. Beta blockers are not dangerous and have been in use for such a long time that it is unlikely that we will see an immediate cessation. But these results are hard to ignore, and cardiologists will be paying careful attention.

Breast cancer risk from alcohol reassessed

Gilbert Ross, M.D.
November 11, 2012

Way back when — say, in 2003 — we thought we had all the information about risk factors for breast cancer that we needed, or at least that we were going to get. These included: early onset of menstruation, few (or no) full-term pregnancies, strong family history of the disease (especially those with the BRCA mutations), postmenopausal obesity, and advancing age, most prominently. The question of how much of a risk — if any — is posed by hormone therapy remains a puzzle, whose final outcome is pending.

Then about 10 years ago, news came from researchers indicating that alcohol, even in moderation, also increased the incidence of breast cancer. Some studies indicated that even 2-3 drinks daily raised the risk by 10-20 percent. Then, only three years ago, a new risk factor was characterized: breast density. Women with particularly dense breasts — meaning with greater concentration of fibro-glandular tissue which appears grey-white on mammograms — got a "double whammy": not only do dense breasts confer a higher risk of breast cancer, but the lighter shadowing pattern on mammograms make true cancers harder to detect. In fact, women with dense breasts are often advised to get an extra diagnostic test, such as an MRI; some states have even passed laws requiring doctors who receive a mammogram report of "dense breasts" to share that information with the patient.

All these risks for breast cancer certainly amount to reason for concern among women, yet with few exceptions the risks are not susceptible to proactive intervention. One cannot change family history, age at menarche, or breast density, for example. Weight loss after menopause, while possible, is frightfully difficult, even with inspiration aimed at reducing the risk of cancer. One modifiable factor: alcohol intake. But now, research has yielded a new perspective: it appears that moderate alcohol intake may well not be of importance for the development of breast cancer after all. A new commentary report from the National Institute on Alcohol Abuse and Alcoholism re-assesses the suspected link between moderate alcohol ingestion and breast cancer.

"Understanding how and when alcohol consumption increases breast cancer risk is important for a full understanding of how moderate alcohol drinking impacts women's overall health," says Philip J. Brooks, Ph.D., program officer in the NIAAA Division of Metabolism and Health Effects. He went on to explain that both the time course and drinking pattern must be considered in relating alcohol drinking to breast cancer risk. In other words, current or recent drinking patterns do not contribute as much as previous lifelong patterns: women who drank heavily in the past or binge drink have a significantly increased cancer risk, even if their current usage is reduced. On the other hand, women who drink only moderately throughout their adult life do not actually have an increased risk. Besides the obvious concerns about drinking and breast cancer, there is substantial evidence that moderate drinking confers various health benefits, especially relevant for heart and vascular benefits.

So avoiding an occasional cocktail may not only add to a woman's daily worries needlessly, but actually detracts from her overall health.

Smoking's deadly toll among women: a new report

Gilbert Ross, M.D.
November 6, 2012

It's been 60 years since the first solid reports of the causal effects of cigarettes and premature death and disease made the news, and almost 50 since the Surgeon General's report made believers out of almost everyone: Cigarettes are killers.

Back then, two-thirds of men and almost half of all women smoked regularly, with the toll of lung and other cancers as well as heart and chronic lung disease rising in parallel with the increasing number of smokers. The dramatic rise in cancer, especially, was blamed on all sorts of environmental chemicals and foods, cleverly abetted by the tobacco industry to distract attention from the real cause. But as the rate of smoking gradually declined over the decades, while the rate of cancer and heart disease fell — albeit with a twenty-year lag period — it became clear to any who wished to see: smoking was the cause of the "cancer epidemic."

In Britain, 23 of the top 30 causes of death are smoking-related, and this same statistic is likely true here as well. Even so, tragically, about one-fifth of us in the U.S. still smoke, 46 million addicted to nicotine. And that includes 18% of women, a figure just slightly below the male smoking rate. Women have come a long way, baby, but there's still have a long way to go.

So a recent study out of the U.K., the "Million Women Study," comes as good news: Among women who smoke, quitting before age 30 reduces the damage from

continued on page 10

Vitamins' cancer magic oversold

Josh Bloom, Ph.D.
November 3, 2012

It didn't take long. Less than one week after a paper in The Journal of the American Medical Association, or JAMA, claimed that multivitamins might prevent cancer, the vitamin ads from drugstores are already piling up in my inbox and mailbox.

After news headlines like "Multivitamins may lower cancer risk in men," it is not surprising that there would be some hype. But I believe that much of this is greatly overstated and originated from the problematic wording of the paper itself — particularly because of the use of a single word: "significantly."

The study protocol itself was sound. Over an 11-year period, almost 15,000 male doctors, all 50 or older were given either a placebo or a common multivitamin supplement, and the risk of all cancers in the two groups was compared.

The long study time, the large number of people enrolled, and the use of a placebo as a control are indicative of a well-run clinical trial.

The final sentence in the medical paper reads: "In this large prevention trial of male physicians, daily multivitamin supplementation modestly but significantly reduced the risk of total cancer."

BOSTON Herald.com

Clinical trials generate enormous volumes of data, and sophisticated calculations are required to process the data and draw any conclusions. An essential parameter called statistical significance determines the mathematical probability that the conclusions derived from the data in the study are real, as opposed to being coincidental. When that probability reaches 95 percent or higher — a universally accepted value — statistical significance has been reached.

Thus, when the authors say "modestly but significantly," what they really mean is modestly and mathematically acceptable.

But just about everyone else will see significantly and read "a lot," which is not even remotely the case.

A careful examination of the paper raises more questions. For instance, although there was an 8 percent reduction in overall cancer risk in the vitamin group compared to the placebo group, this did not hold true for prostate or colon cancers, the most and third-most most common cancers in men, respectively. There was no significant difference between the vitamin and placebo groups in these cases.

Furthermore, there was no significant difference in the cancer death rate between the groups, which is counterintuitive to what you might expect if the stated 8 percent reduction in incidence was real.

Perhaps the most important factor here is that cancer is not a single disease, but rather, a conglomeration of over 100 different diseases. This makes analysis of the results much more complex. Rather than studying the effect of a single vitamin on one disease, the JAMA paper examines the effects of a dozen or so very different vitamins on over 100 very different diseases.

This may explain why the conclusions are murky. Although the 8 percent figure for total cancers was "statistically significant," there was not one single type of cancer for which the 95 percent value was obtained. Scientifically, all of this just doesn't add up.

If the take-home message from this study becomes "take vitamins and you won't get cancer," it will be just one more example of sloppy reporting resulting from a poorly worded sentence. We don't need any more of this. People are confused enough.

Smoking's deadly toll among women: a new report

continued from page 9

smoking by 97%; even quitting by age 40 lowers the risk by 90%! Women smokers who quit before middle age will gain, on average, an extra ten years of life.

The bad news is that even light smokers — those who smoked less than 10 cigarettes daily — had double the risk of dying over the 12-year study period. And among those who continued to smoke, at any level, the overall risk of death was triple that of non-smokers.

The reason why this information is only now being tabulated is that women took up smoking much later than did men — generally around the time of the second World War — and it takes twenty or more years for the damage done by smoking to occur.

It's devilishly hard to quit for highly addicted smokers, and even for lighter smokers it often takes many tries to finally become smoke-free. Unfortunately, the commonly used aids for quitting, such as gum, patches, and drugs, don't help all that much. Other methods still being explored include "harm reduction" via reduced risk tobacco products, such as "snus," a non-chewed form of smokeless tobacco, and electronic cigarettes, which seem to deliver the needed nicotine dose smokers crave, without the deadly smoke toxins.

The main message is clear: It's never too late to quit, and there is no more important step to take to improve your health, to save your life, in fact. So quit now, by whatever means necessary.

Red Bull_ _ _ _

Josh Bloom, Ph.D.
October 26, 2012

Medical Progress Today

If there is any perfect example of how supplement makers get away with murder, this is it.

So-called "energy" drinks are currently in the news because the FDA is investigating whether the deaths of 5 people who drank concoctions with names like Monster and Red Bull, are related to the caffeine content in the drinks. The FDA isn't talking yet, but the idea is certainly plausible. Here's why.

In addition to caffeine, coffee and tea also contain smaller amounts of a nearly identical drug called theophylline. If you are an asthmatic, this name probably sounds familiar, because prior to the discovery of prophylactic inhalation therapies (such as Advair), theophylline–a bronchodilator was the mainstay of asthma management.

Theophylline is no longer the first line treatment for asthma. This is because it has a very narrow therapeutic index (the difference in dose between efficacy and toxicity). So when it was used, it had to be used carefully. So much so, that patients (and I was one of them) regularly needed to have their blood checked to make sure that their theophylline levels weren't too high.

Caffeine and theophylline are very similar in structure and function (in fact, when caffeine is metabolized in the body, it forms theophylline). Their pharmacological profiles are similar, although theophylline is 5 times more toxic than caffeine.

Symptoms of theophylline (or caffeine) overdose include nausea, diarrhea, an increased heart rate, and arrhythmias (irregular heartbeats). Sometimes it gets worse–seizures and death can also occur. And this can be triggered by taking as little as twice the recommended dose–an example of a very narrow therapeutic index.

The recommended daily dose of theophylline is 200-600 mg per day. The highest allowable dose is 900 mg per day (and you wouldn't like this one bit). Suffice it to say that theophylline is not the safest drug in the world. And therefore neither is caffeine in sufficiently high doses. How high?

The LD50 (the dose that is lethal to 50 percent of the population) for caffeine in humans is estimated to be 5000 mg. But in the presence of certain drugs that block caffeine metabolism, this amount can decrease by up to five-fold. There are about 80 drugs, including antibiotics, antidepressants and decongestants) that can do this.

So, in a worst-case scenario, 1000 mg of caffeine (equivalent to 10 No Doz pills) can be very harmful–even fatal.

Yet, a 24 ounce can of Monster Energy Drink supposedly (we'll get to this later) contains between 240 and 550 mg of caffeine. Assuming the higher amount, it is not difficult to see why a 14-year old girl weighing 90 pounds and taking Cipro could end up in the emergency room (or worse) by drinking two cans of the stuff.

How much caffeine is actually in two cans of Monster Energy Drink? No one really knows. This is because these drinks are considered to be supplements and are therefore exempt from FDA labeling requirements.

Now for the idiocy. How much caffeine is actually in two cans of Monster Energy Drink? No one really knows. This is because these drinks are considered to be supplements and are therefore exempt from FDA labeling requirements.

Perhaps I'm being picky, but I'm pretty sure that a drink that has enough caffeine such that two cans of it can possibly kill you really ought to have a label letting you know exactly how much caffeine you're getting. Cosmetics labels list dozens of harmless chemicals, yet Red Bull doesn't have to reveal anything? Welcome to Bizzaro World.

Can anyone in his right mind really call this a supplement? No. Because it's not a supplement. It's a drink containing an unknown amount of a drug that can be really dangerous at high doses. There is nothing "supplemental" about these drinks–they are sugar and water with some number of No Doz pills chucked in.

This is just another example of the pure insanity spawned by the Dietary Supplement Health and Education Act of 1994, sponsored by Senator Orin Hatch of Utah–coincidentally where many supplement companies are based. My editorial in The American Spectator discusses this law in more detail.

Well, congratulations, Senator–you did some damn fine work letting this (and other) garbage be sold with virtually no restriction. Your law is pure Red Bull _ _ _ _. And it might be killing kids.

Women's heart attacks more likely fatal: But why?

Gilbert Ross, M.D.
October 25, 2012

examiner.com

A new report — presented at a meeting of acute cardiac care experts, but not yet published in a journal — reveals that among 5,000 new admissions for heart attack, women died more than twice as often as men while in the hospital.

Not only that, women experienced a longer delay until getting emergency coronary interventions such as angioplasty (catheter removal of a blockage), as well as a higher risk of complications of their heart damage, including arrhythmias (irregular heart beats), some of which can be lethal. And their hospital stays were a full day longer than their male counterparts.

Every minute of delay results in death of heart muscle cells, which is directly related to the complications — both immediate and longer-term — of heart attacks. Some of this avoidable harm cannot be laid directly at the feet of the male-dominated healthcare system: women's heart problems are often non-specific, such as nausea and sweating, which may account for their delay in trying to get help via calling 911 — women waited 60 minutes to call for assistance, as compared to men, who waited only 44 minutes. But once in the 4

In the study just reported, done by researchers in France, three-quarters of the 5,000 patients were male; the women were older, by 69 to 61 years. They were also more likely to have high blood pressure, but less likely to smoke. The main outcome was an in-hospital death toll of 9 percent, compared to men's rate of 4.4 percent: women died at over twice the rate of men. Still, the women who survived had insult added to injury: upon discharge, they received important medications (blood pressure and cholesterol reducers, and blood thinners) at a lower rate than men.

Doctors and women are co-complicit in this tragic situation. Women, especially with atypical symptoms, have a very hard time believing they may be having a heart attack, and seek other, more benign explanations. As someone who worked in ERs over the course of many years, I can attest that doctors — both male and female — have a similar attitude, readily accepting a patient's assertion that their problem is due to "indigestion" or "anxiety." At least until the ECG confirms the diagnosis, which can no longer be denied.

Women do not know, and sadly neither do many doctors, that heart disease is the number one killer of women, as it is for men — not breast cancer, a common myth. It is simply unacceptable in the 21st century to treat women with less intensive diagnostic and therapeutic muscle than we do men. Both patients and caregivers need to have their consciousness raised on this crucial subject. Especially in the ER, doctors and triage nurses need to have their antennae up when a possible heart patient who doesn't fit the typical mold — especially if the patient is a woman — comes in.

Do Vitamins Prevent Cancer? Not So Fast

Josh Bloom, Ph.D.
October 19, 2012

Medical Progress Today

Unless you live under a rock it would have been impossible to miss this week's big story about vitamins preventing cancer in men. A paper by researchers at Brigham and Women's Hospital concluded: "Daily multivitamin supplementation modestly but significantly reduced the risk of total cancer."

Over an 11-year period, almost 15,000 male doctors, aged 50 or older were given either a placebo or a common multivitamin supplement, and the risk of cancer in two groups was compared. The researchers painted a fairly optimistic picture about the utility of vitamins in cancer prevention. But I have a problem with some of it.

First, the concept that cancer is a single disease is clearly false. What we call cancer is in fact, a conglomeration of at least 100 diseases, characterized by the site of origin and cell type. Is it even logical to ask whether a dozen or so vitamins could impact a set of 100+ different diseases in a meaningful way, and by some unknown mechanism?

A simpler version of this study would ask the same question, but confine the study to of one particular cancer, for example breast cancer. But breast cancer itself actually has 10 different types, each differing in the genetic makeup of the tumor, and the response (or lack of it) to a given therapy. So, even a study confined to only breast cancer would be still complicated by the heterogeneity of the disease. If different subtypes displayed different responses you couldn't even accurately make the statement that vitamin supplements (or anything, really) reduced the incidence of breast cancer–only that it reduced certain types of it. And studying all types of cancer together raises the complexity of the study enormously–perhaps to the point that the data is not interpretable.

In fact, the multivitamin study shows a similar pattern. Although there was an 8 percent reduction in overall cancer risk in the vitamin group compared to the placebo group, this did not hold true for prostate or colon cancer–there was no significant difference between the groups in these cases.

Furthermore, there was no significant difference in the cancer mortality rate between the groups, which is counterintuitive to what you might expect if the stated 8 percent reduction in incidence was real.

continued on page 15

The comeback of menopausal hormone therapy (HRT)

Gilbert Ross, M.D.
October 15, 2012

Way back in the 1970s and 80s, when I was in practice, women of a certain age were more or less routinely given some combination of estrogen and progesterone to reduce the ravages of menopause. In fact, such treatment, known as hormone replacement therapy (HRT) was sometimes given without any concern for menopausal distress, but rather to protect women from heart disease. It seemed logical that, since men developed heart and other vascular diseases a decade or more earlier than do women, enhancing women's female hormone levels pharmaceutically would likely render them extra protection.

Mind you, there was no evidence from studies to support this approach, but until a large federal trial was released in 2002, it was standard practice to treat menopausal symptoms like sweats, hot flashes, and mood swings with HRT. Often treatment was continued for years after menopause-related problems had ceased — again, with the idea that women were being protected against heart disease with hormone therapy. Further, it was well known that such treatment helped maintain bone strength and delay osteoporosis, thin bones that can lead to fractures.

This picture changed dramatically in 2002, when the Women's Health Initiative (WHI) study was released.

This NIH trial evaluated various outcomes among over 16,000 older women, half of whom got HRT as compared to the control group who got a placebo, over an average of 5 years. Unexpectedly, not only was there no reduction in heart problems, a slight increase was seen. And there was also a slight increase in breast cancer and vein problems in women on HRT. A decrease in bowel cancer and hip fractures was noted, on the plus side.

Women everywhere, on their own and on the advice of their doctors, stopped taking HRT: the number of prescriptions dropped by about one-half over the next few years. Since HRT was (and remains) the most effective way to reduce menopausal symptoms, many women suffered its travails with minimal relief, out of fear of HRT.

HRT is the most valuable method to relieve menopausal symptoms, and as long as it's used early in menopause and for the fewest number of years needed, it's quite safe.

Over the course of the next 8 years of the decade, however, re-evaluation of the WHI database revealed that the initial announcements were based on inadequate information and incomplete analysis.

The main adverse outcomes — increases in heart events and breast cancer — were confined to the oldest subset of women, who had been on HRT for the longest time. Analysis of the women in the study who were actually peri-menopausal, in the age group from 50 to 55, slight reductions in those disturbing events were found.

As these new data gradually reached the medical community and the population at large, a new message became the standard of care: HRT is the most valuable method to relieve menopausal symptoms, and as long as it's used early in menopause and for the fewest number of years needed, it's quite safe.

Recently, two new studies have been published to add ammunition to this recommendation. In March, a group of 7,500 women, who had also been in the WHI group, was assessed at the Fred Hutchinson Cancer Center in Seattle. They were studied six years after they had been on estrogen-only HRT — only women who have had a hysterectomy can take this type of treatment, since without progesterone, estrogen can cause cancer of the uterus — and a major reduction in breast cancer incidence of 23% was found. And only 2 weeks ago, a Danish research group studied cardiovascular outcomes among over 1,000 women, half of whom had received HRT for about 11 years, as compared to the half who were given only placebo. Again, a reduction in heart problems of 50% was revealed.

There are two important lessons to be learned from the widespread misinterpretations of the WHI data: first, evaluations of such important studies should be done patiently and carefully, and not by press release or wishful thinking; and, women who suffer from moderate to severe menopausal distress need no longer fear HRT — it should be requested or prescribed based upon individual patient criteria and for the briefest period required.

The Tanning Industry Should Be Red-faced

Lana Spivak, M.S.
October 12, 2012

When so-called "tan-a-holic" mother of four Patricia Krentcil made headlines for allegedly taking her five-year-old daughter into a tanning booth, the story elicited mostly disgust nationwide — both for her mistreatment of a child as well as her uncanny resemblance to burnt toast. Krentcil even became the focus of an SNL skit where her look was described as "Wile E. Coyote after something blows up in his face."

But if society can unite to gleefully parody the adverse consequences of indoor tanning, why, then, does this nearly $5 billion industry still attract an estimated 28 million Americans (and growing) each year? Surely more and more people are becoming aware of the harmful effects of UV-emitting tanning devices: In 2009 they were placed in the highest cancer risk category ("carcinogenic to humans") by the World Health Organization's International Agency for Research on Cancer. And given the growing popularity of awareness campaigns that emphasize the dangers of tanning (not the least of which are skin cancer, wrinkles, and vision damage) one might imagine that the fervor for tanning is waning. Yet a 2009 study from the Graduate School of Public Health at San Diego State University found, that in most U.S. cities, there were more indoor tanning salons than Starbucks or McDonalds restaurants.

In addition to multiplying its locations, the tanning industry has attempted to further boost the popularity of the trade by promoting its various "health benefits." For instance, according to an investigation by FairWarning, a nonprofit consumer group, some tanning salons are putting employees through a "D-Angel Empowerment Training" program, which relies on a video developed by the International Smart Tan Network, an industry group. In the video, employees are told that tanning is a good source of vitamin D, which can prevent breast cancer, heart disease, and autism. Suffice it to say, the training video is misrepresenting the facts. While it's absolutely important to maintain adequate levels of vitamin D, its role in preventing cancer and autism is tenuous at best. Yet even still, the Centers for Disease Control and Prevention will tell you that the safest way to obtain vitamin D is through diet or supplements.

But the video doesn't stop there. It also accuses greedy dermatologists and sunscreen makers of conspiring to frighten the public by encouraging minimal exposure to UV light. Unfortunately, they haven't been frightening people enough. A CDC report released earlier this year found that, Caucasian women between the ages of 18 and 21 were the most likely to indoor-tan, with 32 percent acknowledging they would engage in the activity. And among women who had already frequented a salon, the study found that they averaged 28 sessions in the past year.

When it's been established that frequenting a tanning salon before the age of 35 can increase one's risk of melanoma — the most deadly form of skin cancer — by a whopping 75 percent, shouldn't public health officials be taking more action to combat the tanning industry's manipulative PR tactics? Just this summer, the U.S. Preventive Services Task Force reversed a 2003 recommendation by issuing a new draft guideline advising doctors to counsel children, adolescents, and young adults with fair skin about the harmful effects of exposure to UV radiation.

However, though such measures are important, they are not enough — especially when more than 3.5 million skin cancers in over two million people are diagnosed annually. In 2011, the American Academy of Pediatrics joined the World Health Organization in deeming UV-tanning devices highly carcinogenic, and the American Academy of Dermatology went one step further. They issued a policy statement pushing for a ban that would prohibit any minor from indoor tanning. Such laws already exist in California and Vermont, but sixteen states do not currently have any rules at all regulating indoor tanning.

Evidence already demonstrates that 90 percent of melanoma cases are associated with exposure to UV light. Perhaps this, combined with ceaseless national ridicule, finally pushed Patricia Krentcil to meet a journalist's challenge to avoid tanning for an entire month.

More than 3.5 million skin cancers in over two million people are diagnosed annually.

But should it really require a media frenzy to deter just one person from tanning? Absolutely not, which is why it's imperative that states and local communities implement legislation that, just like cigarette laws, bans minors from engaging in this dangerous activity. Physicians and health care professionals also need to be more rigorous when it comes to educating their patients about the harms of indoor tanning. With both initiatives combined, perhaps we can finally begin to make a dent in the terribly high rate of this largely preventable disease — and, in a twist of fate, make the new, non-tan-a-holic Krentcil proud.

Inderal Indatoilet

Josh Bloom, Ph.D.
October 9, 2012

Medical Progress Today

It is very unusual when an old, well-established class of drugs is suddenly shown to be less effective than previous thought. Or even useless. But according to a large study in the October 3 JAMA, this may very well be the case with beta-blockers, a staple of heart and blood pressure treatment since the 1970s. The implications are huge–almost 200 million prescriptions were written for these drugs in the U.S. in 2010 alone.

Inderal (propranalol) was the first drug in a class of non-specific beta-adrenoceptor antagonists(mercifully shortened to beta-blockers) that was launched in 1964 by Imperial Chemical Industries (now AstraZeneca) for treatment of angina. Its inventor, Sir James Black was later awarded the Nobel Prize in medicine for what is sometimes called one of great medical discoveries of the century. Beta-blockers have been used routinely for decades, and there are now about 20 of them to choose from. But should they be chosen at all?

The JAMA authors concluded that:

"Among patients enrolled in the international REACH registry, beta-blocker use was not associated with a lower event rate of cardiovascular events at 44-month follow-up, even among patients with prior history of MI. Further research is warranted to identify subgroups that benefit from beta-blocker therapy and the optimal duration of beta-blocker therapy."

While this is not definitive, it's pretty damning, especially when another study–the second in one week–says pretty much the same thing.

A group at the University of Maryland School of Pharmacy examined post-MI drug compliance in theJournal of the American Geriatrics Society that examined patient compliance following a heart attack. About 50 percent of patients properly took their prescribed medications following a heart attack. As one would expect, patients who refilled their prescriptions for standard drugs, (typically statins, anticoagulants, blood pressure medications and beta-blockers) had a 29 percent reduced risk of dying than those who did not–except in the case of beta-blockers. It did not matter whether these were refilled or not. This is by far the most interesting aspect of the study.

So, what is going on here?

Beta-receptors are molecular switches that are embedded in the surface of cells. When either epinephrine (adrenaline) or nor-epinephrine bind to these receptors this sends a signal into the cell, which is then activated to carry out some function, such as speeding up the heart. This binding and the subsequent response are responsible for the "fight or flight" response.

Blocking of this process in heart cells partially prevents adrenaline from reaching the receptors, causing the heart to slow and beat less forcefully, while also lowering blood pressure. It has long been medical dogma that these effects give the heart "a rest," thus diminishing the frequency of additional cardiac events.

But it seems that popular wisdom is becoming unpopular. I doubt that these studies will result in the immediate cessation of beta-blocker use, but I'm sure that cardiologists will be paying careful attention.

Do Vitamins Prevent Cancer? Not So Fast

continued from page 12

So, in order to believe that headlines, typically like CNN's "Multivitamins may prevent cancer in men," you need to accept that there is some mechanism by which a bunch of vitamins taken over 11 years has a small protective effect against some cancers, and this fails to translate into a lower mortality rate. I dunno. It just doesn't add up.

But the biggest problem I have is the wording of the conclusion: "[M]odestly but significantly." It may be unintentional, but this phrase automatically distorts the real findings of the study. And certainly makes it more newsworthy.

Scientists will understand that this term means modestly and statistically significant–in other words modestly with mathematically acceptable data. Everyone else, including the press, will no doubt read "significantly" as a lot. Which, I suspect is why this story has generating so much interest.

This hype will no doubt send men stampeding toward CVS in a frenzy that will make Pamplona's Running of the Bulls look like walking a poodle. This is the effect that bad headlines and exaggerated claims have on people that are perpetually confused by bad headlines and exaggerated claims.

If the take-home message from this study becomes "take vitamins and you won't get cancer," it will be just one more example of sloppy reporting, possibly encouraged by overoptimistic conclusions. We don't need any more of this. People are confused enough.

Ovarian cancer screening does more harm than good: Federal panel

Gilbert Ross, M.D.
October 9, 2012

examiner.com

Last month, the United States Preventive Services Task Force — an group of 16 independent experts who are charged with objectively evaluating evidence regarding medical tests and procedures — issued its recommendation against screening healthy women of any age for ovarian cancer.

Their evaluation of numerous studies found that neither of the two common methods of detecting ovarian cancer early — a blood test CA-125, and pelvic ultrasound — reliably found cancer early enough to save anyone from death, and in fact led to many false positive results and unnecessary procedures as a result.

The largest study reviewed by the panel was published last year in the Journal of the American Medical Association.

In it, among over 78,000 women between the ages of 55 and 74, half were screened and half were not (the screening tests were those mentioned: CA-125 and transvaginal/pelvic ultrasound). Over the course of about ten years, there was no difference in deaths from ovarian cancer between the two groups. There was, however, an important difference: among the women who were screened, almost ten percent had a false positive result. And almost one-third of those had some sort of surgical procedure done, needlessly. The false positives were attributable to benign ovarian cysts or elevated CA-125 caused by other conditions.

These findings and the panel announcement were particularly distressing since cancer of the ovaries is a highly lethal type: While it is not very common, with just under 23,000 new cases last year, it is very difficult to catch early enough: 15,500 deaths are expected this year, according to the American Cancer Society. It must be emphasized, however, that this advisory does not apply to women at higher risk of ovarian cancer: those with a strong family history of the disease, or those with a genetic mutation increasing the risk (such as BRCA-1 or -2).

Despite the study findings and the panel recommendation, some doctors continue to screen women for ovarian cancer anyway. Sometimes, patients request it, clinging to the mistaken belief that the tests can somehow find the disease early enough to save lives. A physician survey reported in the Annals of Internal Medicine earlier this year, based on responses from over one-thousand doctors, said that about a third of them believed the screening was effective and that many routinely offered it to patients.

The lessons here are twofold: First, doctors fervently desire to find earlier methods to detect potentially lethal cancers, of course — and so do their patients. But that should not blind them to the facts: screening for ovarian cancer does more harm than good, in general, and should not be done without good reason. This is hard for some doctors to accept. More importantly, better diagnostic predictors of ovarian cancer need to be developed to avert the lethal consequences of this silent killer.

Prop. 37 on food labeling: No – Measure is new food ruse

Ruth Kava, Ph.D., R.D.
September 28, 2012

The San Diego Union-Tribune.

As Americans across the country head to their polling sites on November 6 to vote for President, California residents will also have the opportunity to vote thumbs up or down on Proposition 37, which mandates labeling of foods that contain genetically engineered (modified) ingredients. According to its supporters, Prop. 37 is a "right to know" law that will give consumers the ability to avoid genetically engineered (GE) foods that they believe to be less healthful, unnatural, or even dangerous. But this is just a ruse to cover up the misinformation that's been promulgated by activists and those with organic food interests, who stand to gain from spreading baseless fears about GE foods.

The fact is that GE products have been safely consumed by just about every American for more than 16 years, yet opponents typically claim that GE foods have not been tested for safety. But as is the case with the other scary myths promulgated by the anti-GE camp, this is not true. Such foods (or ingredients), just like any new hybrid produced by old-fashioned breeding

continued on 21

B(o)M(b)S away

Josh Bloom, Ph.D.
September 27, 2012

Medical Progress Today

And I thought my investment strategy was bad.

Back in January, Bristol-Meyers Squibb got themselves into the right race, but picked the wrong horse, and it was a very expensive bet.

The company plunked down $2.5 billion to buy Inhibitex, a small antiviral company that had exactly one important asset: a phase II inhibitor of hepatitis C polymerase — the long-awaited, and perhaps final piece of the hepatitis C puzzle. I suspect they must now have quite a case of buyers remorse. After reports of serious cardiotoxicity (including one death) in a phase II trial, last month BMS stopped all development of BMS-986094, formerly INX-189.

Two decades of research have brought the brass ring — an AIDS-like cocktail for hepatitis C–within a tantalizingly short reach. Such a cocktail, a combination of a protease inhibitor (two were approved in 2011) with another drug that acts by an unrelated mechanism, would be expected to be very potent, less prone to generating resistance, and capable of replacing the first-line therapy, interferon–an immune booster that is only modestly effective, and plagued with an array of such awful side effects that it is not uncommon for patients to discontinue treatment, despite the absence of any alternatives.

It was obvious from the onset that the second drug would probably be an inhibitor of RNA replication, a crucial step in viral proliferation that is promoted by an enzyme called hepatitis C polymerase (short for RNA-dependent RNA polymerase).

A number of companies are getting very close, especially Abbott, Vertex and Gilead, but no one has managed to cross the finish line, a place where many billions of dollars await. This is not for the lack of effort. This one has just been a particularly tough nut to crack.

For example, there are 15 approved polymerase inhibitors for HIV (these are called reverse transcriptase inhibitors in the case of HIV), mostly introduced over the course of one decade, but 23 years since the discovery of hepatitis C, there are zero. About two dozen polymerase inhibitors have failed in the clinic thus far, either from lack of efficacy or toxicity, so this is clearly a more difficult target.

Which I'm guessing that the folks at BMS are now well aware of.

A quote from BMS CEO Lamberto Andreotti back in January is of particular interest: "The acquisition of Inhibitex builds on Bristol-Myers Squibb's long history of discovering, developing and delivering innovative new medicines in virology and enriches our portfolio of investigational medicines for hepatitis C."

Uh, no it doesn't. They simply bought a company to get its drug and it blew up in their face– 2.5 billion times.

Announcing the New and Improved ACSH.org

September 25, 2012

ACSH is proud to announce the launch of our brand new website and newsletter! We hope that you will take advantage of the latest features, which include a streamlined design equipped with Facebook, Twitter, Amazon, and email functionalities. We also encourage all readers to log on and register to create an individual profile, which will allow you to comment on any of our daily Dispatch items directly on the website.

AMERICAN COUNCIL ON SCIENCE AND HEALTH

We hope to continue to engage our subscribers with new and interesting content while welcoming them to participate in the discussion through our new comments feature. Readers will also notice a new and improved Dispatch newsletter that will include excerpts of each story. Want to read the article in full? Simply click on it and you'll be redirected to our new site.

Log on now, and happy browsing!

For dense breasts, doctor-patient communication is still the best policy

Roya Heydari
September 24, 2012

AMERICAN COUNCIL ON SCIENCE AND HEALTH

For years, breast cancer awareness campaigns have urged women not to miss their scheduled mammograms. Yet there are some women for whom a regular mammogram is not enough. The latest research shows that women whose breasts are composed mostly of dense tissue can have a mammogram year after year and still have their breast cancer go undetected.

These findings on breast density have gained recognition not only in the realm of biomedical research; they're now beginning to influence legislation. Groups advocating patient awareness have been urging state legislatures to pass a bill that would make it mandatory for a patients' mammography report to include breast-density information. The mandate is now a state law in Connecticut, Texas, Virginia, and — as of this July — New York.

But will such mandates ultimately benefit women? The answer is complicated.

Dense breasts can cloak cancers because of the way dense tissue appears on a mammogram. Dense tissue increases the chances of missing a dangerous lesion because, like cancerous tissue, dense tissue appears as a lighter shade of grey on a mammogram. This characteristic makes it more difficult to differentiate between normal tissue and cancerous lesions. JoAnn Pushkin, founder of D.E.N.S.E. (Density Education National Survivors' Effort), explains that using a mammogram to try to find a tumor in a dense breast is like "trying to find a snowball in the middle of a blizzard." According to a study published in JAMA, she says, breast tumors in women with dense breasts are found only 50 percent of the time – that is, every other woman in this category risks going undiagnosed. Compounding this problem, according to a review published in Breast Cancer Research, women with dense breasts have an even greater risk of developing breast cancer than those who have a first-degree relative with breast cancer.

Given these facts, at first glance it's hard to see what could be problematic about legislation intended to inform women about the presence of dense breast tissue.

However, the problem that may arise with this type of legislation lies in one word: over-diagnosis. It's a phenomenon that's a concern for all women being screened for breast cancer, regardless of their breast density. A recent Norwegian study, published in the Annals of Internal Medicine, found that up to a fourth of breast cancers detected by mammograms would never have resulted in significant disease. In an editorial accompanying the study, Dr. Joann Elmore of the University of Washington School of Medicine and Dr. Suzanne Fletcher of Harvard Medical School observed that, because screening in the U.S. is initiated at a younger age than it is in Norway, over-diagnosis almost certainly occurs more often in this country.

Over-diagnosis is a quickly growing problem here in the U.S. Such unnecessary diagnoses cause not only anxiety and stress; they carry with them unnecessary painful medical procedures such as biopsies and surgeries.

This is not to suggest that, because there are cons as well as pros to the issue, women and their families should do nothing. However, to maximize best outcomes, perhaps mandated individual notices are not in fact the most effective route to take when it comes to breast density. That is, knowledge without an informed dialogue between patients and caregivers may not be helpful in the long run.

By improving communication between doctors, public health agencies, and the public, we can increase knowledge and awareness of the concerns associated with dense breasts. Measures such as public education campaigns, for instance, may very well be a more effective means of dealing with this fraught issue. Whereas a tissue density notification mandate would simply send patients away with a stamp of "dense breast" and a need for further testing, a woman who is aware of her own risk factors can have an informed discussion with her health care provider to determine a tailored course of action. The beneficial upshot would be further testing only for those with higher than average risk.

Dense breasts can cloak cancers because of the way dense tissue appears on a mammogram.

Will a breast density notification mandate lead to a slippery slope of further tests, exacerbating the already serious problem of over-diagnosis? This question cannot be answered with a simple yes or no. On the one hand, women have the right to be aware of their current physical status and the risks that accompany it. However, the problem of over-diagnosis cannot be taken lightly. Patients and doctors must be aware that tissue density notification may go hand in hand with increased emotional stress.

A mandate alone will have a limited benefit. The key to truly making a difference for women with dense breasts is not so different from how healthcare should be practiced across the board: informed communication between doctors and patients.

Simplifying contraception's complexities

Gilbert Ross, M.D.
September 23, 2012

examiner.com

When "The Pill" was developed back in the early 1960s, medical and social philosophers predicted a sexual revolution, as reproductive and sexual fulfillment were, it seemed, finally untied from each other. However, complications ensued.

The sad fact is that the United States leads the world in unplanned, unintended pregnancies. This is especially problematic among our teenage girls, whose lives and plans are so often derailed by such an occurrence. Carrying a pregnancy to term and having a baby as an unwed teen often derails young lives, and of course the alternative —termination of pregnancy — is also tragic when 15- and 16-year olds have to make such a gut-wrenching decision.

Why the high rate of teen — and adult — unintended pregnancies in our technologically advanced society? Ironically, despite the information revolution enhanced by social media and the 24/7 blog cycle, many women are woefully uninformed about contraceptive options and which are the best choices for each individual. ("Abstinence only" sex education, ironically, is responsible to some extent for the "ignorance is bliss" approach to birth control and its devastating consequences).

Some women shun or abandon the pill because of experiences of or fear of adverse effects — which are actually uncommon with the modern low-dose varieties. Condom use requires partner cooperation and appropriate regular use. Both methods result in relatively high failure rates, about 10% or more per year.

Because of these problems, the contraceptive candy store has grown tremendously, giving women of all ages more choices to prevent pregnancy. While this is a good thing, generally, for some women too many choices lead to consequences that could have been avoided.

For instance, in the 1970s and 80s when I was in practice, the intrauterine device (IUD) was a "big deal." It required a minor surgical-type encounter to insert or remove, and was felt to raise the risk of infertility if the woman decided to become pregnant. One type, the Dalkon Shield, was blamed as a cause of pelvic inflammatory disease, a painful infection and a cause of infertility — and the bad rap on it affected thinking on all IUDs up until recently.

Contraceptive implants came along in Europe and Asia in the 1980s, and were first allowed here in the U.S. in the 1990s. Their insertion is simple and painless, and so is removal, with the rapid return of fertility as the contraceptive hormone levels fall to normal with days of removal. Of course, local reactions can occur but are almost always of short duration.

Some women shun or abandon the pill because of experiences of or fear of adverse effects — which are actually uncommon with the modern low-dose varieties.

Now, the American College of Obstetrics and Gynecology (ACOG) issued an "Opinion" calling for more widespread use of long-acting reversible contraception (LARC): IUDs and implants. The ACOG committee said:

"Intrauterine devices and the [birth-control] implant are the best reversible methods for preventing unintended pregnancy, rapid repeat pregnancy, and abortion in young women."

Since over 80% of pregnancies among teenagers are unplanned, and since LARC methods have a failure rate of under 1% per year, it is to be hoped that these methods do indeed become more widely accepted, and that obstacles to that goal are reduced. Two of the main obstacles are: a) lack of knowledge among primary care doctors about the benefits of LARCs, as well as their lack of the skills needed to utilize them; and b) lack of reproductive privacy for teens seeking effective contraception: only 21 states and the District of Columbia allow the decisions about birth control to be made between the teen and her doctor, without interference from parents or spouses.

Further, an international study published one year ago found that women with IUDs had a 50% lower risk of cervical cancer than did women who never had one.

So, women and docs, let's get with the 21st century program. It is not inconceivable — no pun intended — that the epidemic of unplanned pregnancies in our nation, unique in the developed world, can be stemmed to a significant extent if IUDs and contraceptive implants become more commonly utilized to replace the less effective methods now in use. The real beauty of these methods, besides their safety, is that a woman does not have to remember to use them and use them correctly each and every time sexual contact occurs — they are always "on board and ready for action." The only real downside: No protection from sexually-transmitted infections (including HIV) is obtained from these methods, so a barrier method (condoms are best) is also recommended.

An old wives' tale makes a comeback: Cranberry juice

Gilbert Ross, M.D.
September 23, 2012

examiner.com

An old wives' tale makes a comeback: Cranberry juice

When I was in med school and throughout my practice years, the old saw about cranberry juice protecting women from recurrent urinary tract infections (UTIs) was looked upon with disdain, even ridicule. We were too cool to believe such myths, relied upon by our senior mentors and even our moms. Not when we had all those powerful new antibiotics to fight off the bladder invaders. The most frequent offender was (and still is) the bug whose scientific name is E. coli, causative agent of "honeymoon cystitis" — so-called because frequent sex was a known precursor to painful bladder infections in young women.

How times have changed. While E. coliremains vulnerable, by and large, to our most common antibiotics, many other varieties of bacteria have become resistant to multiple antibiotics. Worse, pharmaceutical researchers have been unable to develop many new, effective antibiotics over the past decade or so (although their proficiency in discovered new AIDS treatments remains a modern medical miracle). And evidence suggests that overuse of antibiotics contributes to resistant organisms, such as MRSA, a hospital scourge — as well as being expensive and responsible for allergic reactions when used promiscuously.

Guess what? A recent study found that it's just possible that good ole' fashioned cranberry juice may help to reduce the frequency of recurrent UTIs among women — and men too! (Men can be victims of frequent UTIs, especially if they have enlarged prostates obstructing urinary outflow).

The study authors were based in Taiwan, and they evaluated ten prior studies involving over 1,400 patients, and found that those who consumed over 2 glasses daily of cranberry juice had about one-half as frequent UTIs when compared to those who drank less, or none.

Of course, this is not a "gold standard"-type of controlled trial from which a cause-and-effect conclusion can be drawn. Moreover, other studies have shown, over the years, that the beneficial effect of cranberry juice is modest at best. And cranberry juice, like other fruit juices, is quite caloric and too much of it can pack on the pounds if someone trying to reduce UTIs isn't careful.

Men or women with recurrent bladder infections should of course get checked out by a physician, which will often require referral to a urologist and kidney and bladder X-rays. Also, young women who have a tendency to get UTIs after sex can sometimes reduce their frequency by vigorous hydration — a few glasses of water — before and/or after sex.

One way or another, it is indeed rare for anyone with a normal urinary tract anatomy to have to suffer recurrent infections these days with appropriate evaluation and treatment — even without using powerful antibiotics too often.

Good news about pregnancy and drinking

Gilbert Ross, M.D.
September 19, 2012

examiner.com

If you're pregnant — or even contemplating it — I'm sure you've heard the mantra about drinking while gestating: Just Say No. Everyone "knows" that there's no amount of alcohol you can safely imbibe if you're pregnant. Right?

Well, in a word, no. While many studies document a seriously increased risk of various malformations among newborns of women who binged on booze while pregnant, the consensus of scientific studies shows pretty convincingly that modest amounts of alcohol pose no significant increased risk to the fetus. Surprise!

In the last years of the 20th century, large British and Canadian studies showed (separately) that one drink daily, or less, during the first trimester resulted in no increased risk of so-called "fetal-alcohol syndrome," (FAS), a constellation of malformations generally linked to excessive alcohol use in pregnancy.

More recently, another study from the UK found no problems among over 11,000 children (studied at age 5) of mothers who drank lightly, or moderately (up to 8 drinks per week).

And the icing on the cake, so to speak, comes from an Australian study published in 2010 which seemed to show that infants and toddlers of light-drinking moms actually had generally better health parameters than did abstainers' offspring.

The basis for the "No drink for you!" myth probably derives from studies of heavy drinkers, whose offspring did indeed have a high risk of FAS. Trouble is, you can't just extrapolate from heavy increased risk of so-called "fetal-alcohol syndrome,"

continued on page 21

Good news about pregnancy and drinking

continued from page 20

(FAS), a constellation of malformations generally linked to excessive alcohol use in pregnancy.

More recently, another study from the UK found no problems among over 11,000 children (studied at age 5) of mothers who drank lightly, or moderately (up to 8 drinks per week).

And the icing on the cake, so to speak, comes from an Australian study published in 2010 which seemed to show that infants and toddlers of light-drinking moms actually had generally better health parameters than did abstainers' offspring.

The basis for the "No drink for you!" myth probably derives from studies of heavy drinkers, whose offspring did indeed have a high risk of FAS. Trouble is, you can't just extrapolate from heavy exposure problems down to light use — science just doesn't work that way. Pregnant women do tend to be hyper-cautious about, well, everything. So if someone – anyone — hints at some toxin to avoid, well fuggedaboudit! It's toast.

But really, don't women "with child" have enough real problems to worry about, without having to deal with them all stone sober? Moreover, about half of all pregnancies are unplanned, so it's highly likely that many pregnancies are well underway while the unsuspecting woman has been drinking as usual during those early weeks. Now there's no reason to feel concerned, or worse, guilty about that normal behavior.

My organization, the American Council on Science and Health, covered this subject pretty comprehensively at the time those studies came out: our mantra is to correct health and science mis-information whenever we come upon it.

This is a perfect example.

Prop. 37 on food labeling: No – Measure is new food ruse

continued from page 16

practices, must be shown to be substantially equivalent in terms of safety and nutrition to the earlier variety. And in this respect, GE foods have been tested at least as much as, or in some instances, more than are conventionally produced ones. Further, the FDA already requires foods to be labeled if they contain allergens or new substances that are produced by novel technologies – and no example of GE food causing an allergic reaction just by being made using GE has ever been validated.

Nevertheless, anyone who wishes to avoid GE foods can already do so without any new mandates: Many manufacturers label their products as "GE Free," and of course organic food cannot contain GE ingredients. Prop. 37 proponents argue that some folks can't afford organic foods, which are often considerably more expensive than the conventional variety, and that this law will protect them from "harm." But if Prop. 37 passes, it's likely that even conventional foods will be more expensive, as producers will have to physically sort and separate the foods produced by different methods, as well as change labels for both types. Producers would be charged with the prohibitively difficult task of ascertaining how every ingredient in their foods was grown or produced in order to be sure they comply with requirements – needless oversight leading to increased costs.

However, a more likely scenario that would follow the passage of Prop. 37 is even more damaging: Rather than take on the onerous task of sequestering GE and GE-free products for the California market, food producers and marketers may well just abandon GE methods entirely – as has been the case over most of Europe, where superstitious fear of GE products is rampant. Thus, enactment of Prop. 37 would derail the vast potential for developing new GE agricultural products to boost crop yields and help fend off malnutrition, especially in the less-developed world.

Finally, such supposed "right to know" laws, while sounding very democratic, are prone to unintended consequences. Look at California's Prop. 65 – the law that says any product containing a component known to the state to cause cancer or reproductive harm must be labeled. So what has happened? You can find such warning labels on virtually everything sold in the state. However no one has yet documented a resulting health benefit of all this labeling. Instead, producers of everything from typewriter correction fluid to artificial fireplace logs have either labeled their products or scrambled to reformulate them – and guess what that's done to prices.

In light of the above, it's fair to say that California's Prop. 37 is a shameful, cynical and harmful ruse – designed to make worried consumers think they're going to benefit from the proposed labeling. The problem is that they won't. Instead, they'll see their cost of groceries go up, and may well be frightened enough of the scary label to go organic. This, of course, is precisely what the organic food marketers want and explains why they have been funding the Prop. 37 campaign so vigorously. Why else would they be doing so, since their organic products are already "GE Free"?

Prop. 37 is a bad idea and would be a bad law if approved. It will benefit no one's health, it will raise consumer food costs and stifle a technology with vast potential for real public-health benefit. "Right to know" laws, as with other aspects of public policy, should not be based on spurious, agenda-driven fears.

The coming gonorrhea epidemic

Josh Bloom, Ph.D.
September 5, 2012

NEW YORK POST

Gonorrhea is becoming untreatable. This common and potentially serious sexually transmitted disease was once easily cured. But now, of the 50 antibiotics once used to treat the infection, only one drug works — and just barely.

Bacterial resistance to antibiotics isn't just a problem in hospitals anymore. Resistant bacteria are hitting the streets — and we lack the tools to deal with the growing crisis.

The bacteria that cause gonorrhea have grown resistant to all other antibiotics; ceftriaxone, the sole survivor, is hanging on for dear life. To preserve its efficacy, the Centers for Disease Control and Prevention has come up with new guidelines for treating the infection.

Rather than being handed pills, patients must now get an injection of ceftriaxone accompanied by a second oral antibiotic. This will slow the progression of bacterial resistance to the drug, but it won't stop it.

There is no way to win the resistance war against bacteria. Over time, even with the most prudent use of antibiotics, resistance is all but certain. The best we can do is to "keep up" with the germs by discovering new antibiotics that will kill the resistant strains.

Yet the federal Food and Drug Administration effectively discourages research into new antibiotics.

During the late 1990s, the FDA suddenly decided to require "better" statistical power for clinical trials of antibiotics by requiring companiesto enroll about twice as many subjects, making trials much lengthier and prohibitively expensive — yet no more medically relevant.

Dr. David Shlaes, the former vice president of infectious disease research at Wyeth, found himself squarely in the middle of this battle in 1999. After countless meetings with the FDA over a three-year period, he finally convinced the agency to postpone its new clinical requirements so that Wyeth could continue the development of its antibiotic Tigacyl, which would have otherwise been dropped.

The absence of robust antibiotic discovery programs threatens to profoundly alter the practice of infectious disease medicine, to some extent binging us back to 1940, before antibiotics were available.

Back then, Shlaes predicted that if the FDA didn't reverse course, it would bring antibiotic research in the US to a screeching halt. He was right — research died.

One by one, drug companies pulled the plug on their antibiotic programs — including, ultimately, Wyeth.

We're now starting to pay dearly for this. Only two new antibiotics have been approved in the United States since 2007, compared to an average of four a year in the 1980s. Only four of the 12 major drug companies remain in this area of research at all.

The absence of robust antibiotic discovery programs threatens to profoundly alter the practice of infectious disease medicine, to some extent binging us back to 1940, before antibiotics were available.

We are now this close to having no drugs to treat gonorrhea — an infection that 300,000 Americans a year contract even when we have antibiotics to control it.

The nation is looking at a very scary public-health problem.

Warns Shlaes, "This is a train wreck already in motion. As other resistant bacteria continue to work their way through the general public, we will soon be seeing more cases of pneumonia and urinary tract infections that will be impossible to treat."

There is at least a glimmer of hope. At a lecture in May, Dr. Janet Woodcock, director of the FDA's Center for Drug Evaluation and Research, said that the agency will soon "reboot its approach to antibacterial development."

Shlaes hopes it is not too late: "If the FDA does not reboot soon, Americans will be left to fend for themselves with increasing numbers of untreatable infections. This will be very bad indeed."

Good news about breast cancer — Part II

Gilbert Ross, M.D.
August 29, 2012

examiner.com

In my previous essay on breast cancer, I discussed how the effective treatment of breast cancer in a pregnant woman does not have to compromise the health of either the mom-to-be, or her baby-in-waiting. This commentary advises women at above-average risk of breast cancer about the means to protect themselves against ever developing the feared disease.

It has been widely known — by medical scientists, oncologists (cancer specialists), and some ob-gyns and primary care docs, that there are drugs that can actually prevent breast cancer from developing. Well, not prevent completely: the drugs reduce the risk of getting it by 50 percent or more. Of course, like just about all drugs, these drugs — called "chemoprevention" agents — have some risk of side-effects. And they are not for everyone: They are recommended only for women who have a significantly elevated risk of breast cancer.

There are a few proven risk factors that increase a woman's chances of breast cancer. Most important among them is family history. If more than one first-degree relative (mother, sister, or daughter) had breast cancer, one's risk goes up substantially. This is especially true if a relative was diagnosed at a young age — before age 40. And if several relatives, whether close or more distant, had the disease, it is advisable to check for the high-risk mutations, BRCA-1 and BRCA-2. The other important risk determinant is simply age: risk increases significantly with advancing age, and the majority of breast cancers occur among women over age 70.

The other factors together confer only a slightly increased risk: most cancers occur without any apparent cause. That being said, these factors play some causative role:

- young age at menstruation onset
- no full-term pregnancies
- menopause after age 55
- prolonged use of progestin-containing hormone replacement therapy
- certain benign breast conditions, including fibrocystic disease
- obesity in the post-menopausal years
- and a recently discovered factor: unusually dense breasts.

Some evidence also suggests that excess alcohol intake and previous radiation therapy to the breast areas may increase cancer risk.

In order to assess a woman's estimated relative risk, all these factors can be fed into a risk assessment model computed from nationwide statistics and available through the National Cancer Institute, called the Gail Model.

For women whose projected five-year risk of breast cancer is significantly elevated, according to the Gail criteria, there are actually several drugs that can reduce the risk by more than half. For women not yet in the postmenopausal years, a drug used for over thirty years to prevent recurrence of breast cancer has also been shown to prevent its initial development: tamoxifen. More recently, a similarly acting drug, raloxifene (Evista), was found to have an even stronger protective effect in a head-to-head comparison with tamoxifen.

For higher-risk older women, those who are post-menopausal, a group of drugs called aromatase inhibitors have been shown to be quite effective in reducing the risk of breast cancer.

For higher-risk older women, those who are post-menopausal, a group of drugs called aromatase inhibitors have been shown to be quite effective in reducing the risk of breast cancer. While all of these drugs have some potential adverse effects, the benefit of preventing many cases of breast cancer is often the deciding factor. After all, about 230,000 new cases of breast cancer occur in our country each year, and almost 40,000 deaths result — thankfully, this number has been gradually on the decline.

Yet amazingly, these drugs are not being used nearly as often as they should be. At a recent medical education conference, Dr. Jennifer Diamond, an expert in breast cancer prevention, estimated that well under one-tenth of the 2 million women who should be on chemoprevention therapy are actually receiving one of these drugs.

Worse, fewer than one in ten of the physicians attending her course were familiar with the concept, much less the actual drugs.

Since this approach has been documented as effective and FDA-approved (at least, the older, so-called estrogen-modulating drugs tamoxifen and raloxifene are) it is to be hoped that the learning curve for American physicians will soon catch up with the research. The potential to significantly reduce the tragic toll of breast cancer is too important a goal to tolerate the current state of medical ignorance and apathy about breast cancer chemoprevention.

Good news about breast cancer — Part I

Gilbert Ross, M.D.
August 29, 2012

Pregnancy should be a joyful experience. Thus, the discovery of a breast lump while pregnant comes as an especially fearful development, and if the subsequent biopsy report confirms a malignant growth, depression — even panic — may occur. The natural fear for one's own health is multiplied by concern for how treatment might harm or even end the new life in the womb.

A new report from a European group of researchers, however, has demonstrated that chemotherapy for breast cancer can be administered to pregnant women with satisfactory outcomes for both baby and mother. In other words, there is no need to compromise the mother's treatment, nor interfere with the pregnancy: the cancer can still be fought effectively.

The incidence of breast cancer among pregnant women has risen over the past decade or so, as more women postpone childbearing and mammography screening has become more prevalent. Yet, there is no reason for most women to be alarmed: Breast cancer at age 40 and under is still rare. But for those unfortunate few, the new study provides some comforting news.

The scientists evaluated over 400 women with early breast cancer, half of whom received typical combination chemotherapy; they were then compared to the group that delayed chemo treatment until after delivery. While those who got treatment while pregnant delivered prematurely somewhat more often, there were no other significant differences between the two groups. (In both treated and untreated mothers, complications occurred more often with earlier deliveries, but the chemotherapy itself was not the determining factor.)

Further, disease-free survival after treatment was the same in both groups, regardless whether treatment was administered during pregnancy or delayed until after delivery.

These findings surprised me and the other experts at my organization, the American Council on Science and Health. We have become inured to the seemingly-continual alarms over tiny levels of this or that common chemical supposedly causing all sorts of health effects. Yet here's a study showing that the most vulnerable targets — fetuses — are relatively immune to big-time doses of really toxic chemicals. The simple message is this: Women with breast cancer while also preparing for new motherhood, take heart — in all likelihood, your baby will be fine, and so will you!

Flu vaccine and pregnancy: perfect together

Gilbert Ross, M.D.
August 29, 2012

Pregnant women are renowned for avoiding any substance, food or ingredient that they believe might pose the slightest threat of harm to their unborn child. Traditionally, the list of shunned products has included medications, coffee or tea (or both), even a drop of alcohol, and needless to say, cigarette smoke.

What about vaccines? While there is at least a semblance of scientific support for avoiding many of the exposures I mentioned above, what's the story with immunizations against preventable contagions — microbes that can possibly harm both mother and fetus?

Medical scientists have long known that the protection conferred by vaccines for pregnant women far outweighs any possible risk of harm from the shots. Unfortunately — much like the widespread but completely unjustified fear of children's vaccines — moms-to-be also have a strong tendency to avoid getting vaccinated. The most recent stats show that only about 40 percent of pregnant women have received the seasonal flu shot — and that was even an improvement from only a few years ago. The 2009 "Swine flu" scare convinced many women to forego their fears and get vaccinated, and some of that reasoning has, thankfully, taken hold.

Now, a just-published study from researchers at the University of Texas in Dallas re-affirms that vaccination against influenza in early pregnancy — the first trimester — is not only safe, but actually promotes better outcomes for both mother and newborn.

A group of researchers in the Ob-Gyn department at the University of Texas Southwestern Medical Center in Dallas evaluated nearly 9,000 pregnant women who received the influenza seasonal vaccine, and compared their pregnancy experiences, including deliveries, and those of their newborns, to those of 77,000 women who failed to get immunized. The results showed that — not only were there fewer birth defects and stillbirths among the vaccines — but there was a lower rate of neonatal death (within the first month of life) among the infants whose mothers got the vaccine.

We know that flu vaccination is safe and effective — but we didn't fully appreciate its manifold benefits for pregnant women, until now. Since a key factor in getting those hyper-cautious pregnant women to accept the vaccine is advice from a doctor, it is to be hoped that obstetricians of those

continued on page 25

Cereal Killers

Josh Bloom, Ph.D.
August 23, 2012

Medical Progress Today

With apologies to my attorney friends, the saying "95 percent of lawyers make the rest of them look bad" remains one of my favorites.

And a story in yesterday's New York Times did little to change this. The lawyers who were involved with negotiating the Tobacco Master Settlement Agreement (MSA) of 1999 (and made obscene amounts of money in the process) are now going after food manufacturers using a similar strategy. This is almost funny.

According to the Times, Don Barrett, a lawyer in Mississippi earned a mere $200 million from the MSA, but he apparently can't live on that, so he and his well-meaning colleagues are suing ConAgra, a giant Nebraska-based food company, for mislabeling a number of their products, including the always-dangerous Swiss Miss cocoa.

Mr. Barrett says, possibly even with a straight face, that "It's crime–and that makes it a crime to sell it." He and the rest of his merry men want the products in question taken off the shelves. I feel safer already!

And clearly in the interest of humanity everywhere, his group might seek damages equaling four years of sales for all mislabeled products. The fact that these guys stand to make billions of dollars does, I concede, tarnish their philanthropic credentials somewhat, but I'm still sure that they mean well.

The food industry is not without blame either. Their marketing practices haven't been exactly pristine. Taken at face value one might conclude that, given the number food items labeled as "healthy" and "natural" (in the obligatory green package), anyone that eats a granola bar should theoretically be immortal. And another thing–am I supposed to be surprised that my milk is "Raised By Farmers?" As opposed to lingerie salesman or bassoonists?

This is going to create all sorts of problems for marketing departments at food companies, since pretty soon they will run out of chemicals that they can boast that are excluded from their foods. Most of the deadly poisons like sugar, salt, artificial colorings, artificial sweeteners, preservatives, gluten, lactose and corn syrup are already proudly trumpeted as being absent from so many products. What will the next gimmick be? Plutonium-free eye drops? Delicious Pop Tarts– no tapeworms!

While this may sound stupid, if you didn't read the Times article, you haven't even been exposed to the true meaning of the word yet.

In 2009 two mothers sued PepsiCo, claiming that Cap'n Crunch's Crunch Berries did not actually contain berries. In a ruling that ranks right up there with the Dred Scott decision, a federal judge threw the case out stating that "a reasonable consumer would not be deceived into believing that the product [contained a fruit that does not exist]."

I should hope so, because anyone with the IQ of plankton pretty much knows that one is just as likely to find a Steinway grand piano in the damn box as a berry. I suppose the decision could be reversed on the grounds that Quaker is misstating the Cap'n's military record, and the cereal should really be named Lt. Crunch.

Should history repeat itself, it is worth taking a look at how the MSA played out. The money paid by Big Tobacco ($252 billion over 25 years) protected the industry from lawsuits from individual states, and was intended to be used to fund anti-smoking programs.

How did that work out? Not all that well really, since only about 3 percent of the revenue was actually used for anti-smoking programs, however, plenty of it was used to plug state budget deficits, build bridges and highways and other ways that states spend our money.

In the end, Big Tobacco, looking to cut their losses, "agreed" to a shakedown by lawyers representing individual states, which, instead of funding anti-smoking programs simply grabbed the money and used it as a bank account. The addicted smokers got next to nothing, but this was hardly true for the lawyers–they got between 10 and 25 percent of the take depending on the state they represented–tens of billions of dollars.

Government at its finest.

So, by all means, let's repeat this process. Another big payday for the tobacco lawyers, decreased revenues for the food companies, which will no doubt be passed on to you, and something approaching zero public benefit. All in the name of Crunchberries.

Is this a beautiful country or what?

Flu vaccine and pregnancy: perfect together

continued from page 24

advocating the necessity for moms-to-be to get vaccinated!

The new study confirms numerous previous researches on the same topic. In 2010, scientist from the University of Washington-Seattle studied a group of over 1.100 Native American moms and their newborns. Half got flu shots, half did not; the results showed that both the women and the babies who got the shot had substantially lower risk of contracting influenza, and a huge reduction in severe flu requiring hospitalization.

This is so important because (among other reasons) newborns up until age 6 months are not eligible to get their own vaccination, so they are dependent on their mothers for immunity — as with so many other things!

So moms-to-be, and moms already, for your own sake and that of your growing babies, get that flu shot as soon as possible: flu vaccination season is here!

A vaccine that prevents cancer — that's not being used!

Gilbert Ross, M.D.
August 16, 2012

Is there a safe, effective vaccine that not only protects young people from the most common sexually transmitted infection (STI) in America, but also protects them from a wide variety of cancers later on? If I were to tell you that such a vaccine exists, but only a small minority of teens receives this protection, would you be shocked, surprised?

This is not some vain, pie-in-the-sky hope: it's real. A vaccine against the common human papillomavirus (HPV) has been available for five years now — in fact, there are now two similar vaccines, and they're both safe and effective. And as it turns out, HPV not only causes STDs, such as genital warts, it also is the primary cause of cancer of the cervix.

Studies have shown that girls who receive the vaccine before they get exposed to the virus, usually in their late teens, are almost completely protected from precancerous changes of the cervix. Cervical cancer still affects ten thousand, killing four thousand victims each year in the U.S.

examiner.com

If parents followed the science — and common sense — there would be a rush on doctors' offices, kids in tow, demanding the inoculation immediately. Yet, for a variety of reasons, only about one-quarter of girls and young women who should be vaccinated, actually get the three shots required for full protection.

Some of the reasons for this unacceptable ignorance of or disdain for the HPV vaccine's protection include: the cost; myths about vaccinating pre-teens and teens against a sexually-transmitted infection somehow encouraging experimentation; and generalized anti-vaccine fears. Because of the large numbers of Americans — especially younger age groups, teenagers — who are exposed to HPV each year, the low uptake of the vaccine presents both a huge public health problem, and an enormous opportunity for benefit.

Consider these facts: Each year, six million of us become infected with HPV; at any time, 20 million are infected; and over half of sexually active women — and men — pick up HPV at some point. Most of the time, our immune systems fight off the virus, just like a cold. But sometimes, the infection persists: it's those persistent cases that can lead to cervical cancer.

And it's not just cervical cancer — and it's not just girls. It takes two to tango, as they say, and HPV transmission (like all STIs) goes both ways. Men who have HPV are at higher risk of genital warts, and also of cancers of the penis and anus. Women also are at increased risk of anal cancer — a recent tragic example was former Charlie's Angel Farah Fawcett. And recent studies have shown that both sexes are susceptible to oral and pharyngeal (throat) cancer from HPV.

So now that you know the facts about HPV and the safe, effective vaccine to thwart its potentially lethal effects, why not make sure your kids get vaccinated. The best time to get the shot is before their first possible exposure to HPV: before they start having sex, in the age group 9 through 16. But if they missed that window, they still can benefit, probably, up to age 26. And that includes boys, too. Remember, an ounce of prevention applies to HPV as much as anywhere else!

Can your lipstick cause diabetes? No

Gilbert Ross, M.D.
August 15, 2012

Friday the 13th seemed like it would be really bad luck for American women, as the toxic alarm was blared all over the news: scientists at a prestigious hospital had found a "link" between a chemical present in many cosmetics, and diabetes! And the recent rise in obesity rate has heightened everyone's awareness of the dire consequences of obesity-related diabetes.

So now, would doctors be advising women who use cosmetics (that is, all the female patients of primary care physicians)

examiner.com

to go without makeup? Lipstick? Fragrance? Nail polish, self-tanners, even shampoo? That would be a most unlikely and unwelcome scenario. Thankfully, despite the alarmist, breathless headlines and TV sound bites, the study upon which the hysteria was based was flawed beyond any semblance of scientific validity. The researchers analyzed the level of the chemical — actually chemicals — in question in urine specimens from over 2,000 women, and tried to find a relationship between the chemicals, called "phthalates" (pronounced tha-lates) and diabetes. See also my organization's discussion of this topic: "From eyeliner to diabetes? Not so fast." When I say "tried," I mean they really, really tried. And in this type of "scientific" investigation, if one tries hard enough to find some association, one often can. But the methods used and the conclusions they drew are not based on real evidence of a true causal relationship between phthalates and diabetes. The types of chemical they found were not even the type of phthalate found in cosmetics!

continued on page 28

The Contraction Of Pharma Means Innovation Goes Out With a Bang

Josh Bloom, Ph.D.
August 9, 2012

Given all the analyses and post-mortems of America's pharmaceutical industry, it is impossible to avoid the notion that a "lack of innovation" has left the industry in its current, sorry state.

Whether this is true or simply a platitude remains to be seen; yet, the decimation of the industry caused by a decade of massive job cuts virtually guarantees that however little innovation we had in the past, there will certainly be less of it now.

About four million Americans are infected with the hepatitis C virus, and 200 million people worldwide—roughly 4 percent of the world's population—are infected.

Perhaps the best recent illustration of pharmaceutical innovation and its subsequent impact on human health is the story of how drug companies tackled hepatitis C, a serious viral infection of the liver that is a global epidemic. Hepatitis C has only recently been receiving substantial media coverage, but it is, in fact, a very big problem.

In the 1990s, antiviral research was focused mostly on AIDS, but during that time, virologists were also starting to tackle hepatitis C, a lesser known, but arguably just as important, infectious disease.

About four million Americans are infected with the hepatitis C virus, and 200 million people worldwide—roughly 4 percent of the world's population—are infected. This is four-fold higher than the number of HIV-positive people worldwide. If left untreated, hepatitis C causes cirrhosis (scarring of the liver), and can progress to liver cancer, end-stage liver disease and death. In fact, most liver transplants performed in the U.S. are a result of hepatitis C-induced liver failure.

Unlike most viral infections, hepatitis C is unusual in that it often takes decades following infection for symptoms to appear. As such, there are millions of people in the U.S. without any idea that they are infected. That's because in the pre-AIDS era, exposure to blood—the primary means of transmission of the hepatitis C— was of little concern. This permitted hepatitis C to spread by multiple routes, including transfusions, needle sharing, dental procedures, tattoos, and rarely, via sexual contact.

Since baby boomers contracted the infection decades ago, they are only now starting to feel the effects of the disease as their livers begin to fail. There are 80 million boomers, so this is something of a ticking time bomb, set to go off very soon.

It's a good thing, then, that pharmaceutical innovation was still alive and well a decade or two ago.

Until last year, treatment options for hepatitis C were poor. The cure rate was only about forty percent and the therapy contained the immune stimulant interferon—a drug with such awful side effects that it wasn't uncommon for patients to discontinue the six-month treatment, even though doing so might very well be a death sentence.

But last year, after twenty years of intense research, two new hepatitis C drugs were approved. Either drug taken in combination with the interferon regimen resulted in cure rates that were almost double. This was a huge improvement; however, interferon was still required.

Yet this, too, is about to change.

The holy grail of hepatitis C therapy—an AIDS-like cocktail without interferon—is very close. So close, in fact, that some doctors are advising their patients to wait for the anticipated approval of a four-drug pill from Abbott Laboratories, which has demonstrated a previously unimaginable 95 percent cure rate in late stage clinical trials.

Innovative new drugs have beaten down HIV and hepatitis C, the two most important viral infections on in the world. Remember what AIDS used to be, and consider what management of hepatitis C would be like without these new medicines.

Unfortunately, should we be faced with a similar challenge today, the outcome will likely be very different. The infrastructure, manpower and brainpower required to duplicate such a campaign are fading away. Infectious disease research is a shadow of its former self.

The ongoing contraction and decline of the American pharmaceutical industry virtually guarantees that innovation will suffer. We have seen what it can do. Its absence will affect all of us.

Calling the FDA's bluff and saving smokers

Gilbert Ross, M.D
August 7, 2012

The Examiner WASHINGTON

In a recent Op-Ed for Reuters, FDA Commissioner Margaret Hamburg boasted about the success of the 2009 Family Smoking Prevention and Tobacco Control Act. The news would be quite welcome – if only it were true.

Unfortunately, the effectiveness of the new law's various measures is nil. Its ban on candy cigarettes and requirement that cigarette makers divulge their ingredients will save exactly zero smokers. And the FDA's recent attempt to impose large graphic health warning labels on cigarette packages and ads is another empty gesture: Most studies show that such graphic labels have no impact. Dr. Hamburg's praise for the enforcement actions in the law would be appropriate, except that those rules were enacted first by the Tobacco Master Settlement Agreement in 1999.

Worse still, some of the prospective measures the FDA aims to implement will actually be counterproductive. For example, Hamburg claims that FDA researchers are aiming to reduce the addictiveness of tobacco products. However, reducing the level of nicotine will actually prove detrimental to smokers. A decrease in nicotine levels will likely cause smokers to smoke more cigarettes, thus inhaling more carcinogenic smoke, in order to get their nicotine fix.

The Tobacco Control Act also hurts public health by creating huge obstacles to tobacco harm reduction. Simply put, this method allows nicotine-addicted smokers to satisfy their craving with their drug of choice, but without the tobacco smoke that is the real killer. While nicotine keeps smokers coming back for more, it's the smoke — inhaled hundreds of times a day — that causes the numerous smoking-related diseases.

Tobacco harm reduction is based on the same concept that led to the development of nicotine patches, gums and inhalers. Yet the sad fact is that the FDA-approved cessation products have been proven ineffective in study after study. The best of them increase "successful" quitting from 5 percent to maybe 10 percent — hardly anything to crow about. These products fail to deliver the nicotine "hit" that smokers require and do not replace the taste and rituals of smoking.

The options provided by tobacco harm reduction do — and they are simply more effective. In Sweden, a tobacco product called "snus," smokeless tobacco sold in small teabag-like sachets, has been shown to help reduce smoking rates and smoking-related disease to the lowest level in Europe. Snus-type smokeless tobacco does not cause any of the cigarette-related diseases — and, of course, there is no secondhand smoke.

There are many other reduced-risk tobacco products and "clean-nicotine" devices as well. These include dissolvable oral orbs and sticks, and electronic cigarettes ("e-cigarettes") that look like cigarettes but deliver a vapor of nicotine in a solution that is inhaled like cigarette smoke.

Given the recent uptick in smoking in less developed regions, one would expect public health leaders worldwide to embrace such promising technology. Alas, they haven't. In fact, the international tobacco control treaty of 2003 (the World Health Organization Framework Convention on Tobacco Control) specifically urges governments not to investigate these nearly harmless and beneficial products, but to ban them first and develop reasons later.

No doubt, much of this resistance stems from the reprehensible activities of cigarette companies in decades past. But the goal now should be saving millions of American lives — and a billion others. The Centers for Disease Control and Prevention, American Cancer Society, FDA and others refuse to acknowledge that reduced-harm nicotine delivery products help smokers quit, whereas conventional FDA-approved patches and gum do not.

More than 450,000 lives are lost to smoking each year in our country alone, and multiples of that number are left too ill to work or enjoy life. The numbers are even more tragic in developing countries. Most smokers wish to quit, yet few succeed. All the while, our leaders issue platitudes and refuse to tell the truth. It is long past time that this should change. Smokers, and the families they leave behind, are the real victims of this public health embarrassment.

Can your lipstick cause diabetes? No

continued from page 26

And a "one-moment-in-time" analysis like this one cannot possibly support the authors' self-promoting assertions, such as "diabetes linked to cosmetics," a scare story eagerly swallowed and spit out by the media.

These days, everyone on the media health beat seems to be caught up in spreading anxiety about all the "toxic" chemicals all around us: in our food, water, air — and our beauty products. This dovetails neatly with the increasing (and real) concern about obesity and its common, lethal sidekick, diabetes. But let's keep it real: obesity is caused by over-consumption of calories, especially modern extra-large portion sizes of everything; matched with too little exercise. If we all got off our behinds more, stepped away from the keyboards and played some ball or ran, or even walked, the "obesity epidemic" would be stymied.

But to many, diet and exercise are a tough sell; it's easier to blame "chemicals" of one sort or another, relying on such poorly done and over-hyped studies as this one to promote an agenda instead of lifestyle education. The good news: our cosmetic products and fragrances have been in widespread and safe use for many decades, and there's nothing to fear when using them as always. So, to your good health, and beauty!

Progress against AIDS, but no time for complacency

Gilbert Ross, M.D.
August 6, 2012

examiner.com

For those of us who had the tragic, frustrating experience of caring for AIDS patients in the last two decades of the 20th century, advances announced at last month's International AIDS Conference in Washington were nothing short of miraculous.

Our nation's drug regulators, the FDA, approved a pill to markedly reduce the transmission of HIV, the virus that causes AIDS, among high-risk patients who were HIV-negative. The drug — Truvada — is actually a 2-drug combination, and to achieve maximal protective efficacy it must be taken every day. But given the numbers of HIV positives in America, any reduction in transmission will yield significant benefits in terms of both lives saved and healthcare expenditures.

The other breakthrough was the approval for widespread use of a rapid, private, at-home test for HIV using saliva, not blood. This test — called OraQuick — costs only about $60 and gives a result in about one-half hour, with good (but not perfect) reliability.

Why is this test so important? The statistics about AIDS in the U.S. are surprising, indeed disturbing. Despite having several types of drugs to control (but not cure) HIV, fifty thousand Americans contract the virus each year, and almost twenty thousand die. While these figures are dwarfed by the epidemic's toll in Africa, Asia and Eastern Europe, given our advanced healthcare system, this toll is unacceptable. So why is it such a serious ongoing problem? Doesn't everyone know by now how to avoid contagion, and control it if infection occurs?

Well, yes and no. There are about 1.2 million HIV positive Americans, and one-fifth of them — 240 thousand — do not even know they are infected! It goes without saying that if you don't know you're HIV positive, you're not going to be too concerned about passing it on to a sex partner.

The virus has reared its ugly head with increasing frequency because many who should be, don't bother to get tested

Those at highest risk of contracting the virus are men who have sex with men (MSM), women partners of HIV-positives, and intravenous drug users. This has been well known almost since the epidemic began here in 1981, but even then — when being an HIV carrier was a death sentence — many people in high-risk groups continued to practice unsafe sex, or to share needles with other addicts of unknown HIV status.

Vigorous educational campaigns helped to reduce unprotected sex among MSM — until, paradoxically, the discovery and development of numerous effective drugs against HIV's proliferation led to an attitude of complacency. One isn't going to be quite as careful about asking tough questions of a new "friend," nor in using condoms each time, when the virus can be considered a treatable chronic disease, versus a lingering death sentence.

The virus has reared its ugly head with increasing frequency because many who should be, don't bother to get tested: a "head in the sand" attitude, leading to lack of safe sex practices. Only about one-third of HIV patients are getting effective treatment, an unbelievable failure of public-health outreach. Those groups most likely to have and transmit the virus and get infected are the same groups least likely to be on good treatment: the young, black, and poor.

Modern anti-retroviral drugs, if taken as directed, would reduce viral loads to such a low level that not only would the patient not get sick — they would be unable to spread the infection, with or without condoms.

Why has the disease not been tamed, then?

- Complacency mixed with fear of learning the truth, as I mentioned;
- Fear of being identified, among friends, family or co-workers;
- Expense: of seeing the doctor, of getting the (older) test, and especially of the medications: HIV pills' costs run from a few hundred to over one-thousand dollars each month. Comprehensive, often employer-based health insurance will cover most of that cost, but the government-sponsored insurance for the poor, Medicaid, often does not (it varies from state-to-state).

This discussion illuminates why the recent advances may well prove to be a "tipping point" in the battle against AIDS. If a simple, rapid, private at-home test for HIV is widely available, hopefully a significant fraction of those whose HIV-positive-status is not known to them will find out, and take appropriate measures. And the pill to prevent infection in negative patients should also help to reduce transmission.

Does these new modalities mean the end of the AIDS epidemic? No. But they could indicate that the end is in sight.

Breast or bottle? The decision is not black and white

Gilbert Ross, M.D.
July 31, 2012

examiner.com

A new mother is faced with many important issues and must make key decisions while still in the fog of post-partum joy — and pain, and confusion. One such decision is whether to breastfeed or "hit the bottle": infant formula.

It has become fairly common knowledge that, from the perspective of baby's overall health, exclusive breastfeeding for the first six months has the edge over the bottle. Breast milk enhances baby's immune system, seems to reduce the risk of obesity later on, and often provides a uniquely pleasurable bonding experience for both parent and child.

Nevertheless, new moms are unable or unwilling to devote the rather large amounts of time and effort towards this goal. The reasons why new moms reach for the formula are many, ranging from necessity to purely optional or convenient. There is no "wrong" answer to this situation: while in recent years, more women are choosing to give breastfeeding a try, not too many years ago bottle-fed babies were the norm — and no harm came to them.

The various pressures and concerns of the fateful decision — breast or bottle — were eloquently and elegantly outlined in a recent column in The New York Times by Jane E. Brody: "The Ideal and the Real of Breast-Feeding."

Adding to the pressures on women to breastfeed, New York's Mayor Bloomberg has now taken it upon himself — as is his style — to attempt to dictate to new mothers what their choice should be. In a cleverly-named campaign, Latch On NYC, he and his cronies in the NYC Department of Health have "persuaded" a majority of the city's hospitals to place significant obstacles in the path of those who want to consider feeding their little ones with formula. He has gotten those hospitals maternity areas to lock up formula as though it was morphine, and prevented access to the products unless the reason for the request is "documented" and the patient, the new mom, first must receive a lecture on the benefits of breastfeeding.

No matter if the woman is well aware of these facts yet chooses to use formula; or if she is unable to breastfeed, as many are; or if she cannot possibly commit to months of breast-pumping due to family conditions or her minimal maternity leave from her job — without which baby, mother and family will become impoverished. If they want the formula, they must get the "educational lecture." The Mayor says, "I know breast!"

This latest foray into telling New Yorkers what's good for them is in keeping with the Mayor's highly aggressive health campaigns — some of which have been beneficial (banning smoking almost everywhere), others not likely to be so (banning sodas over 16 ounces). In this instance, one thing will definitely occur: women will feel coerced into making an important decision, under the most confusing and vulnerable circumstances, which may well be not in their best interests, nor those of her infant and her family.

Every new baby and its mother are different; all are individuals with different needs and circumstances. To force all into one special box — breastfeed only — is an egregious intrusion into a highly personal and private issue. My own organization covered this topic recently as well: "Let's go easy on moms who don't breastfeed."

The government has no role to play in this decision, and should mind its own business: governing should be a full-time job, leaving no room for playing surrogate daddy.

Qsymia is Not Fen-Phen

Josh Bloom, Ph.D.
July 30, 2012

Medical Progress Today

If there is one medical area where drug development has been hampered by extreme caution, it is obesity. Despite the "epidemic" of obesity and its associated type II diabetes we hear so much about, new weight loss candidates have been handled by pharmaceutical companies and the FDA as if they were Kryptonite.

This is clearly due to the fallout from the fen-phen debacle of 1997, when Wyeth was forced to withdraw the two-drug combination pill called Redux because of serious side effects — heart valve damage and, in rare cases, a fatal lung condition called primary pulmonary hypertension. In addition to the people who suffered or died from these side effects, the withdrawal of Redux was a major blow to patients struggling to control their weight, since it was pretty much the only effective weight loss drug available at that time. Even after the withdrawal was announced, some people desperately tried to buy the remaining inventory, since it was the only drug that ever worked for them.

The unfortunate legacy of Redux was a visceral association between diet drugs in general and heart problems. This resulted in extreme caution in the field, and is a major factor behind the 13-year interval between the withdrawal of Redux and the recent approval of two new weight loss drugs,

continued on page 33

ACSH's official commentary on the Bloomberg Administration's proposed ban on sales of super-sized sugary drinks

July 25, 2012
COMMENT ON PROPOSED AMENDMENT OF ARTICLE 81 OF THE NYC HEALTH CODE
By Ruth Kava, Ph.D.,
Senior Nutrition Fellow

For: The American Council on Science and Health
July 24, 2012
1995 Broadway, Second Floor
New York, NY 10023
PH: 212-362-7044
Fax: 212-362-4919
www.ACSH.org

Background

The American Council on Science and Health (ACSH) is a consortium of leading physicians and scientists who are concerned that the public receive accurate, science-based information about public health matters. Our objective is to restore science and common sense to personal and public health decisions, in order to foster a scientifically sound and sensible public health policy for the American people.

The proposed regulation to establish the maximum size of sugary beverages offered and sold in New York City food service establishments is based on the supposition that such restriction will lower the calorie consumption and thus the prevalence of obesity among New Yorkers.

We concur that obesity is a significant health threat, and that obesity in the young points to earlier acquisition of morbidities such as type 2 diabetes than has previously occurred. Yet recent data indicate that in New York City, at least, the proportion of young school children that are obese has actually declined somewhat in the last few years. We note that this welcome decline has occurred without the institution of governmental restrictions on beverage size.

Further, consumption of excess calories from any source, not just calorically sweetened beverages, will lead to weight gain and should be discouraged. But calorie consumption from a variety of foods has increased substantially over the last few decades.

For example, while calorie consumption from caloric sweeteners increased by approximately 9.5% between 1970 and 2009, energy intake from added fats and oils and dairy fats increased by 45% over the same period of time. Thus a focus on sweeteners as the major cause of obesity seems inappropriate. Indeed, a focus on a single source of calories, or a single food is inappropriate, likely to be ineffective, and might even be counterproductive.

Although increasing portion size has likely been a contributing factor to increased food consumption, studies that have demonstrated this effect have typically been performed under controlled conditions. It has not been shown that a mandated restriction on size of beverages sold has an effect on calorie consumption. Indeed, it is certainly possible that consumers who want larger sizes will simply purchase more than one of the allowed smaller containers, thus circumventing the intended goal of reducing calorie consumption.

The proposed restriction constitutes an unwarranted experiment on New Yorkers, without their consent and should not be imposed upon them.

---

1. Centers for Disease Control and Prevdention. Obesity in K-8 Students — New York City, 2006-07 to 2010-11 School Years Morbidity and Mortality Weekly Report 2011;60(49):1673-1678.

2. USDA/Economic Research Service. Average daily per capita calories from the U.S. food availability, adjusted for spoilage and other waste. http://www.ers.usda.gov/data-products/food-availability-%28per-capita%29-data-system.aspx accessed July 1, 2012.

3. Wansink B, Painter JE, North J. Bottomless bowls: Why visual cues of portion size may influence intake. Obesity Research 2005;13(1):93-100.

More Nonsense From Nature Nuts

Josh Bloom, Ph.D.
July 18, 2012

Medical Progress Today

I couldn't let this one go by. Just too slanted and inaccurate. And it's all over the news today.

"Aspirin Isn't a Wonder Drug," is a fine piece of science fiction by "The People's Chemist," Shane Ellison. Ellison also wrote "Over-The-Counter Natural Cures." His credentials, such as they are, consist of a Masters degree in organic chemistry.

Sounds impressive, but it really isn't. Pretty much anyone with the intellectual capacity of plankton can get one.

Thus, it is not surprising that his statements that are carried by multiple news organizations are off scale in their wrongness. Here are some of them:

"Big Pharma didn't invent aspirin. Mother Nature did,"

No she didn't. Aspirin exists nowhere in Nature.

"Thousands of years ago, humans witnessed injured bears gnawing on the bark of white willow trees and people have been using that natural remedy for thousands of years."

So? Thousands of years ago people believed that the sun circled the earth (which was flat), lightning was caused by angry gods, lead could be converted into gold, and drilling a hole in your head would relieve migraine headaches. Thousands of years ago you lived to be thirty and then something ate you.

"White willow bark doesn't contain ASA (acetyl-salicylic acid) or aspirin. Therefore, it won't accidentally kill you.

No it doesn't. It contains salicin, which is converted to salicylic acid upon ingestion. *That* can kill you. Salicylic acid is almost always used almost topically–for acne, dandruff and warts. But it is also the active ingredient in Doan's Pills, which are supposed to help with back pain. Here are the warnings from the bottle:

- chest pain, severe dizziness, shortness of breath, slurred speech, problems with vision or balance;
- sudden numbness or weakness, especially on one side of the body;
- feeling like you might pass out;
- black, bloody, or tarry stools;
- coughing up blood or vomit that looks like coffee grounds;
- blood in your urine, urinating more or less than usual;
- hearing problems, ringing in your ears;
- swelling, rapid weight gain;
- easy bruising or bleeding, unusual weakness, fever, chills, sore throat, flu symptoms;
- fast or pounding heartbeats;
- severe stomach pain, ongoing nausea or vomiting; or
- dark urine, jaundice (yellowing of the skin or eyes).

Great stuff. And–it barely works. Aspirin is about five times more potent than salicylic acid for pain and fever relief.

"Trash aspirin, use white willow bark and hawthorn," he said.

No. Trash the article.

"The industry couldn't market the natural ingredient as their own. You can't patent Mother Nature."

More nonsense. You might not be able to patent all of Mother Nature, but you can certainly patent the use, isolation, and methods of purification of synthesis of any useful drug that is obtained from her. Many chemotherapy drugs are plant-derived drugs. They were patented.

To have a monopoly, they had to alter it a bit. Chemist Carl R. Gerhardt was the first to do so in 1853. He created a molecular cousin and named it ASA (acetyl-salicylic acid). Bayer trademarked it as aspirin in 1889.

Yes–Bayer altered it. To make it work. And the correct name for ASA is acetylsalicylic acid. No hyphen.

"The small molecular change made for big dangers," he said. "Like deflating a tire, aspirin depletes the body of life-saving nutrients."

Sure. People all over the world are starving because they took Bufferin. Speaking of which, wouldn't this make a great TV show? "Bufferin the Vampire Slayer."

I think I'll patent that.

Breast cancer myths — and realities

Gilbert Ross, M.D.
July 16, 2012

examiner.com

A recent study researched and reported by a major Federal advisory panel, The Institute of Medicine, should give both comfort and concern to women — and their families — about breast cancer.

http://www.iom.edu/Reports/2011/Breast-Cancer-and-the-Environment-A-Life… and http://archinte.jamanetwork.com/article.aspx?articleid=1182553

The IOM was called upon by the Susan G. Komen for the Cure advocacy organization to investigate the evidence about the real causes of breast cancer. Happily, along the way, the report also issued some news that should bring relief to many women concerned about non-factors involved in breast cancer causation.

It has long been known that certain factors do play a role in increasing a woman's chances of getting breast cancer. These include:

- early-onset of menses
- never having been pregnant

continued on page 33

Breast cancer myths — and realities

continued from page 32

- post-menopausal obesity
- strong family history of breast cancer, especially at younger ages
- having the BRCA-1 or BRCA-2 mutations: the strongest factor of all

Except for the last factor, all the others increase risk only minimally: most cases of breast cancer have no specific precursor, and this lack of predictability is one of the reasons it inspires such anxiety and fear among women. A more recent addition to this list is having dense breasts, detected on mammograms. The density both increases the risk of the disease, and also makes it more difficult to detect on a mammogram. Women with especially dense breast are often advised to have special studies done, such as ultrasound or even MRI in addition to the routine X-Ray mammogram.

Getting back to the IOM report: The panel evaluated a wide spectrum of "environmental" (meaning non-genetic) exposures, which had been thought to contribute to increasing breast cancer risk. The good news is that none of the suspected chemicals some groups accuse of causing the disease were shown to do so. Exonerated by the IOM: DDT, BPA, phthalate plasticizers, benzene, and other industrial chemicals and pesticides.

On the other hand, the scientific panel cautioned women about the increased risk they felt might be a result of excessive exposure to ionizing radiation in the form of CT scans. In fact, that was the only exogenous (non-genetic) factor they expressed caution about, except for long-term hormone replacement therapy. As a breast-cancer advisory report, they advised avoiding unnecessary CT scans to reduce that specific risk. My organization, The American Council on Science and Health, weighed in on this important issue at that time: http://www.acsh.org/factsfears/newsid.3692/news_detail.asp

However, that advice makes sense for everyone, doctors and patients alike, since medical science does not know how much (or how little) X-Ray exposure can lead to cancer. The trick of course is deciding which CT scan or X-Ray test is unnecessary. It's fairly easy to make that determination after the fact, but in the heat of a potentially serious condition where immediate diagnostic imaging is required, a woman is unlikely to demand justification for a scan if the doctor orders one.

But often, the situation is not so urgent, and the doctor may want to get "one more test, just to be sure." This is often done to protect the doctor — not the patient — out of fear of being sued later. In those cases, it's perfectly appropriate for a woman to ask a few simple questions:

- Is this scan really necessary to help you diagnose my condition?
- Can another test be done instead without radiation — say, a sonogram?

Of course, the real risk of inducing a cancer from one (or even a few) CT scans is quite remote, so a wise patient would comply if the ordering physician sticks to his or her guns. Discretion is the better part of valor in that circumstance.

Qsymia is Not Fen-Phen

continued from page 30

Belviq (lorcaserin) and Qsymia (formerly called Qnexa).

Although the two new drugs both have frightening warning labels, there is no scientific reason to expect that either should have the same side effect profile or risks associated with Redux. This is due to differences in the chemical structures between both drugs.

Fen-phen was an abbreviation for fenfluramine, a stimulant and phentermine, an appetite suppressant, which has been used for more than forty years. All of the adverse effects of Redux were attributed to the "fen" component. And it wasn't actually the fenfluramine itself that was the problem– it was the major metabolite, norfenfluramine, which is formed by breakdown of the parent drug in the liver.

Norfenfluramine then binds to a subtype of serotonin receptors in the heart, causing an over-proliferation of cells in cardiac valves which leads to fibrosis and subsequent valve damage. Phentermine cannot form norfenfluramine and has not been implicated in the cardiotoxicity from Redux.

Therefore, Qsymia, which contains phentermine and another drug, topimerate (an anti-seizure medication), in place of fenfluramine should be no more likely to cause heart damage than any other new drug.

Yet this did not stop the anti-drug group Public Citizen, formed in 1971 by Ralph Nader, from using their now-familiar scare tactics.

Spokesman and perennial drug-hater Dr. Sidney Wolfe declared it to be "magical and delusional thinking for anyone to believe that a drug will turn off hunger without hitting other targets where it will do harm, usually to the cardiovascular system."

Well, I may be delusional, but I disagree. There is no reason that an appetite suppressant should necessarily cause cardiac toxicity. The problems caused by Redux were caused by a specific metabolism of the fenfluramine component–not the fact that it happened to affect one's appetite. The linking of these two phenomena is scientifically illogical.

As with any drug, Qsymia will have side effects in some people. But to focus simply on the risk without considering its benefit is the typical scare-mongering technique of anti-pharmaceutical activists.

Obesity is a serious problem, with its own long list of serious health effects. To dismiss any new pharmacological therapy because of problems with past drugs is foolish and does a disservice to the millions of people in this country who are struggling with serious weight problems.

Mr. President, sign that user fee bill

Josh Bloom, Ph.D.
July 9, 2012

MEDCITY | News
News, Opinion and Analysis From Today's Medical Cities

It's not often Congress acts in a genuinely bipartisan fashion. When it does, there's almost certainly a serious national interest at stake.

And genuine bipartisanship was in full effect a few weeks ago when the House of Representatives voted by a stunning 387-to-5 margin to pass a piece of legislation reauthorizing the Prescription Drug User Fee Act, or "PDUFA."

Just days before, the Senate passed its version of the bill. In conference, lawmakers ironed out the minor differences between their two bills — and now, it heads to the President's desk. Party leaders have said they hope to present President Obama with a final bill by July 4.

It's critical for the President to sign this measure quickly. Doing so will ensure patients continue to have access to top-flight, lifesaving medicines.

PDUFA was first passed back in 1992, when the Food and Drug Administration (FDA) was severely underfunded and understaffed. At the time, even though the agency was supposed to review new medicines within 180 days, it often took two years or more for a drug to make it through the review process.

Lawmakers addressed this issue by requiring drug companies to pay user fees to the FDA when submitting treatments for approval. The fees would help finance FDA review by providing adequate funding for staff and related resources. And it put the financial burden on drug makers, not taxpayers.

This was a smart move.

Shortly after PDUFA passed, the FDA expanded its review staff dramatically. The results have been nothing short of spectacular. The average review time has been cut in half. And patients have benefited from having quicker access to new treatments that can extend and enhance their lives.

By law, PDUFA must be reauthorized every five years. And it's no less important today than it was in 1992. As the sponsors of the most recent version of the bill, Sens. Tom Harkin (D-Iowa) and Mike Enzi (R-Wyo.), have pointedly put it: "This bill can literally save lives by ensuring that Americans have access to crucial medicines and medical devices."

As the sponsors of the most recent version of the bill, Sens. Tom Harkin (D-Iowa) and Mike Enzi (R-Wyo.), have pointedly put it: "This bill can literally save lives by ensuring that Americans have access to crucial medicines and medical devices."

If PDUFA reauthorization is delayed, tens of millions of dollars in FDA financing would evaporate. Hundreds of staffers would be laid off. The approval process would take substantially longer. And patients would have to suffer through punishing new lag times before accessing needed drugs.

Unfortunately, there are some anti-PDUFA forces. They're convinced the FDA is just an extension of the pharmaceutical industry and that this bill further cements that unholy alliance.

But there's zero evidence that such a relationship exists. If PDUFA was just a means of the drug industry bribing FDA for approval of sub-par products, there would have been a steady rise in approval rates since PDUFA first passed.

In fact, the opposite has happened. In 1992, 78 percent of late-stage drugs were approved. By 2006, the figure had fallen to 57 percent. Today, it stands at 45 percent.

The FDA has gotten more — not less — rigorous since user fees were established. These resources are helping to speed up the decision-making process. The agency is moving much quicker — without any compromises in patient safety.

There are an estimated 300 high-tech pharmaceutical treatments currently being developed by the American drug industry. They're aimed at a host of conditions, including asthma, cancer, herpes, malaria and Alzheimer's disease.

If private firms finish one of these new drugs — and it's indeed effective and safe — the FDA needs to quickly approve it and get it patients. PDUFA ensures federal officials have the resources they need to do just that.

Congress has already acted in a exceptionally bipartisan fashion to pass this bill. Now, the President needs to sign it.

Running from breast cancer

Gilbert Ross, M.D.
July 8, 2012

examiner.com

While everyone knows — don't they? — that regular aerobic exercise is good for your circulation and waistline, few are aware of another important benefit: reduced risk of breast cancer.

Despite practicing internal medicine for 20 years, I only learned of this recently, when my public health group, the American Council on Science and Health, reviewed a new study for our daily newsletter.

A group of scientists from the University of North Carolina-Chapel Hill compared thousands of women, half of whom had breast cancer and half cancer free. They analyzed the women's exercise histories, seeking a link between recreational physical activity, done at different time points in life, and the risk of developing breast cancer. (They also tabulated information about other possible risk factors for breast cancer, and adjusted the exercise-cancer results accordingly).

Here's what they found: Women who exercised either during their reproductive or postmenopausal years had a reduced risk of developing breast cancer. Women who exercised 10 to 19 hours per week experienced the greatest benefit with an approximate 30 percent reduced risk. While it may seem like a lot of time spent exercising, the authors included household

continued on page 36

Manufacturing Purer Snake Oil

Josh Bloom, Ph.D.
July 3, 2012

Medical Progress Today

Friday's Chicago Tribune ran an interesting story on how quality control problems at many dietary supplement manufacturing plants were causing unsafe products that were making people sick.

Interesting, yes, but they completely missed the point.

The article mentioned a few cases, including a factory where a half of a rat found next to a scoop used to fill containers with protein powder. This puzzled me, since I cannot imagine how a half of a rat could possibly climb all the way up a table.

Then there was a case of some imbeciles that poisoned their four-year old with a vitamin "supplement" that contained a little extra selenium–200-times more than it was supposed to contain, and infinity-times the amount of supplemental selenium that should be given to the kid (none).

Yet, this stuff was sold by chiropractors and health stores, probably recommended by a cashier who dropped out of high school. (Of the two, it is not obvious who is less qualified to dispense medical advice.)

The question that the Tribune story should have addressed is why any of this stuff–pure or otherwise–should be sold at all.

But the supplement industry gets away with murder because of the Dietary Supplement Health and Education Act of 1994, a masterpiece of greed and ignorance pushed through Congress by Senator Orin Hatch (whose state, Utah is the home to many supplement manufacturers) and two medically ignorant colleagues, Representative Dan Burton (Indiana) and Tom Harkin (Iowa), who are both firmly in the anti-vaccine camp of crazies.

My March 16 op-ed in The American Spectator talks in detail about some of the absurdities of the law and how supplement manufacturers can skirt FDA authority (and common sense) by using certain doublespeak that ostensibly avoids making specific medical claims.

The key to getting away with this is by use of the word "supports."

When you see a label that something "supports prostate health," mentally substitute "this will fix your prostate," and the real intent of the label becomes evident. And worse, good luck finding a label that doesn't say "natural" or "organic" on it. This disingenuously implies that a given product is safe by exploiting consumer ignorance of the fact that neither of these terms have anything to do with safety, but everything to do with marketing.

And worse, the terms "natural" and "organic" also imply that these products are not drugs by virtue of being natural. This is doubly wrong. Not only are supplements drugs, but they are untested drugs–mostly immune from the authority of the FDA, although there have been some recent, but anemic attempts to get a handle on this.

I could go on for days about the garbage that is being legally sold in health stores. Some of these products include anabolic steroids, amphetamine-like stimulants and toxic metals (silver, in particular). These are supplements? What exactly are they supplementing? An amphetamine deficiency?

The term "herbal" is an especially powerful magic word that unlocks the vault of ignorance (and money). But this is just more nonsense. My 2005 op-ed on the American Council of Science and Health web site debunks the science-fictional aura surrounding the word. For now, suffice it to say that Poison Ivy is actually an herb.

It is surprising that a prestigious newspaper like the Chicago Tribune could take an important issue and turn it into a story that actually promotes ignorance by implying that by simply getting a few rat heads out of a supplement makes it OK to take.

It is not. Purer garbage is still pure garbage.

Running from breast cancer

continued from page 35

and occupational activities in their tally, in addition to recreational "exercise."

http://www.ncbi.nlm.nih.gov/pubmed/22733561

And here's even more good news: women who only began exercising during their post-menopausal "golden" years still benefitted from a significant reduction in breast cancer risk.

That study was published in Cancer: A Journal of the American Cancer Society. In that same issue, another expert in breast cancer and exercise noted the large number of prior studies showing similar reductions in breast cancer among women who exercise even moderately; specifically, any activity that was of at least moderate intensity, as long as it was maintained over periods of time. The intensity need not be greater than a brisk walk!

No one knows precisely why exercise has such an effect on breast cancer; and one downside should be noted — weight gain eliminates that beneficial effect.

Bottom line: Ladies, if you keep active, no matter your age or available time, your heart health and your breast health will benefit.

MEDIA APPEARANCES & INTEVIEWS

September 21, 2012

Dr. Ross debates flame retardants on Diane Rehm Show

As we reported just last week, fear of flame retardants is back in the news once more. While we always do our best to explain why the various flame retardants found in furniture do not, in fact, pose a toxic threat, just yesterday, Dr. Ross took on the issue in a more public — and resistant — forum: National Public Radio's Diane Rehm Show. We encourage you to head over to the show page to listen as Dr. Ross attempts to counter the alarmist claims of the other guests.

September 13, 2012

Dr. Bloom schools HuffPo on "toxic" chemicals

Watch Dr. Bloom explain why those "toxic" chemicals frightening people away from Johnson & Johnson products are actually quite safe.

THE HUFFINGTON POST

August 15, 2012

ACSH featured in new video at Giving Library

You can now learn more about ACSH, courtesy of a video viewable at The Giving Library, a site that informs potential donors about non-profit organizations and allows them to more easily connect. Please watch the short video to learn more about our latest efforts and activities; you just may be convinced to help us in our unique endeavors to promote sound science as the basis of public health policy.

giving library™

About ACSH

The American Council on Science and Health (ACSH) is a national, non-profit, tax-exempt 501 (c) (3) consumer health education and advocacy organization based in New York City that is dedicated to providing the public with scientifically based information on the relationships between human health and chemicals, foods, nutrition, lifestyle factors and the environment.

ACSH was founded in 1978 by a group of concerned scientists who wished to ensure that peer-reviewed science was used to formulate personal and public health policies and decisions. Led by its Founder and President, Dr. Elizabeth M. Whelan, guided by a Board of Trustees composed of prominent business, science, policy and civic leaders — and advised by a Board of Scientific Advisors of over 350 of the nation's leading scientists, physicians, and policy experts, ACSH has distinguished itself as one of the most influential public and environmental health advocacy organizations in the nation.

ACSH's mission is to ensure that peer-reviewed mainstream science reaches the public — and the decision-makers who make public policy — in order to foster a scientifically sound and sensible public health policy for the American people. ACSH is committed to improving communication and dialog between the scientific/medical community and the media, in an effort to ensure that that the media's coverage of health issues, which reaches the American public, be based on scientific facts — not hyperbole, emotion and ideology.

ACSH is supported by the tax-deductible donations of private foundations, corporations, associations and concerned citizens. More information on ACSH and its scientific positions can be found online at ACSH.org.

American Council on Science and Health

American Council on Science and Health
1995 Broadway, Second Floor
New York, New York 10023-5860
Tel. (212) 362-7044 • Fax (212) 362-4919
URL: http://www.acsh.org • Email: acsh@acsh.org