INTERNATIONAL HEALTH NEWS

William R. Ware, PhD - Editor

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Your editor is just back from the annual meeting *Orthomolecular Medicine Today,* which he has been attending for a number of years. The three-day conference is generally held in late April and alternates between Toronto, Ontario and Vancouver, British Columbia. Next year it will be in Vancouver. The audience is made up of MDs, NDs, other healthcare professionals, researchers and a few members of the general public who are attracted by the titles of the talks being presented or just attend to be educated. The presentations are intended as reviews and platforms for presenting controversial views in various areas of medicine, although the conferences historically were focused mostly on psychiatric areas. The presenters, mostly from the US and Canada, are highly qualified experts in the areas under discussion and frequently have both clinical and research experience.

The term *orthomolecular* was coined by Linus Pauling of vitamin C fame in 1969 to denote the use of naturally occurring substances, particularly nutrients, in maintaining health and treating disease. Orthomolecular medicine describes the practice of preventing and treating disease by providing the body with optimal amounts of substances which are natural to the body (orthomolecular.org). Readers will recognize that this represents a significant component of the underlying philosophy of IHN. Most readers of IHN are probably unaware of this meeting and some may wish to consider attending.

Among the topics in the program at this meeting, those of particular interest to readers of IHN included the following. This sample of lecture titles also illustrates the nature and focus of the conference. This can be viewed as alternative medicine at its best and the presentations are based on peer-reviewed literature and clinical experience.

- *Controversies in Nutrition: Calcium—the Toxic Nutrient,* Tom Levy, MD
- *Thyroid Dysregulation, and the Metabolic roots of Cancer,* Ron Hunninghake, MD
- *Orthomolecular Cardiology: Unmasking the Magnesium Link to Multiple Cardiovascular Risk Factors,* Alleen Burford Mason, PhD
- *Helping Patients to Overcome Psychosis and Schizophrenia: a Clinician's Experience with the Orthomolecular Approach,* Jonathan Prousky, MD
- *A Holistic Approach to Iodine Deficiency,* David Brownstein, MD
- *Lipoic Acid's Effects on the Mitochondrion and Human Disease Modification,* Bert Berkson, MD

The issues indicated are obviously important, should be of general interest to readers of IHN, and in some cases address serious misconceptions or unappreciated problems common in mainstream medicine. In a future issue of INH, summaries of some of these talks will be provided.

In this issue of IHN vaccination is prominent with the discussion of three aspects, the US Vaccine Court, acetaminophen and autism, and the efficacy of the vaccine associated with new recommendations for pneumonia vaccination in children and those over 65. In addition, the feature subject concerns the risks and benefits of coffee consumption, a topic that should be of very general interest.

Wishing you and your family good health,

William R. Ware, PhD, Editor

Highlights

COFFEE: GOOD, BAD OR A NON-ISSUE?

After water, coffee is the most widely consumed beverage in the US. Two-thirds of American adults drink coffee on a daily basis. Tastes range widely from those who pay little attention to what they drink to aficionados who have experimented with countries of origin, types and blends until a satisfactory solution is found, and they generally use only freshly ground beans. Rather like wine, especially red. Given this high level of consumption, in excess of 400 million cups per day, small benefits or risks can have very important public health implication and many misconceptions exist concerning these issues. Even if one restricts attention to human studies, the impact of coffee consumption on biomarkers has been carefully studied. However, for clinically relevant endpoints, there appear to be very few randomized controlled trials, only case-control and follow-up studies. However, this so-called epidemiologic data turns out to be sufficient to allow meta-analysis or pooled study analysis of most of the important questions.

The principal active ingredient in coffee is caffeine and the amount per cup depends on the species of coffee, how it is roasted, and how the extraction is carried out, including drip, percolation, boiling the ground coffee, using a so-called French press or espresso. Caffeine concentrations per 8-oz cup range from 100 to 350 mg. Energy drinks with added caffeine exceed this only if about three times this volume is consumed. However, coffee contains a large number of chemicals possessing a wide variety of biological actions, and there is reason to believe that in many cases a neutral or beneficial balance occurs in spite of the adverse effects of some of the individual components in this beverage on various biomarkers.

The impact of coffee on health has recently been reviewed.[1, 2] The reader is referred to these reviews for citations concerning individual diseases discussed below.

CORONARY HEART DISEASE

Case–control studies performed in the early 1990s suggested an increase in coronary risk linked to coffee consumption. However, variable results were obtained in follow-up studies. When all the clinical studies were examined up to 2008, no adverse effects of coffee were found and in fact evidence indicated that women experienced a beneficial effect from moderate consumption. Coffee was also not associated with elevated risk in patients who had experienced a heart attack nor was any evidence of risk elevation found for any form of cardiovascular disease. However, there may be a transitory elevation of risk of heart attack immediately after coffee intake in non-habitual drinkers and individuals at high risk.

STROKE

Two meta-analyses have indicated a weak protective effect for stroke associated with coffee consumption and the same transient effect is observed as mentioned above with coronary heart disease events.

ARRHYTHMIA

Observational studies almost uniformly indicate that coffee does not increase the risk of atrial or ventricular arrhythmia and in fact, in a recent and large study there was a slight but significant decrease in risk of hospitalization for arrhythmia and the Framingham Heart Study found no association between caffeine intake and atrial fibrillation. Nor has any evidence been found to connect coffee consumption and sudden cardiac death, an important point since sudden cardiac death is a major component of overall cardiac mortality.

HEART FAILURE

Moderate but not high coffee consumption appears inversely related with the risk of heart failure. The mechanism that produces this J-shaped relationship is unknown. In fact, because coffee contains a large number of potential active ingredients aside from caffeine, it will be some time before a detailed understanding of protective mechanisms is understood.

DIABETES

One of the most well established benefits attributable to coffee involves the reduction of the incidence of type 2 diabetes. A meta-analysis (study of studies) involving over 500,000 individuals found every additional cup of coffee reduced the risk of incident type 2 diabetes by 5 to 10% after adjusting for potential confounders.[3] This study also found a protective effect for both decaffeinated coffee and tea although for these beverages there were fewer studies. Some studies found significant protective benefit only with large daily consumption, e.g. ≥ 4 cups.

Recently published research based on the famous Nurses' Health Study and the Health Professionals Follow-up Study (men) examined the impact of either increasing or decreasing coffee consumption on the incidence of type 2 diabetes. Over a 4-year period, increasing consumption lowered the risk and decreasing consumption increased the risk in subsequent years.[4]

LIVER DISEASE

Evidence based on reduced levels of liver enzymes suggests coffee defends liver cells form damage independent of whether the aggressive agent is a virus, drugs, alcohol or other agents. There are also studies suggesting reduced risk of cirrhosis of the liver. It has been suggested that the mechanism is partly an anti-inflammatory action related to the blockage of certain receptors in the liver. Caffeine is in general considered to be pro-inflammatory but this may be an oversimplification.

NEUROLOGICAL DISEASES, MULTIPLE SCLEROSIS

Two studies have provided significant evidence of a protective effect of coffee on the incidence of Parkinson's disease. On the other hand, studies concerning Alzheimer's disease or progression to dementia have been inconsistent and controversial.

At the 2015 annual meeting of the American Academy of Neurology in late April, studies were presented which indicated high coffee consumption is associated with reduced risk of developing MS. In a US study, non-drinkers were about 1.5 times more likely to develop MS than those who drank ≥ 4 cups a day in the prior year. In a Swedish study, non-coffee drinkers had about 1.5 times the risk of MS as persons who drank at least 6 cups per day in the prior year. It was hypothesized that caffeine is the neuroprotective agent by suppressing the production of pro-inflammatory cytokines.

CANCER

Meta-analyses have been used to enhance the statistical power due to the shortage of individual studies. The results for the common sites of cancer have been either neutral or in some cases suggestive of protection. On balance, the results appear inconclusive as compared to earlier studies which found increased risk. It has been suggested that the in the context of cancer prevention, caffeine might behave similarly to immunotherapy as exemplified in the design of modern cancer vaccines.

COFFEE AND MORTALITY

A meta-analysis has just appeared involving dose response (cups per day) and mortality from all causes, cardiovascular disease and cancer.[5] Twenty-one studies involving almost a million participants and over 100,000 deaths were included. For all-cause mortality, the maximum risk reduction was seen at 3-4 cups per day, and benefit remained almost constant out to 8 cups per day. Cardiovascular mortality exhibited a maximum risk reduction at about 3 cups per day but significant risk reduction was seen even at 8 cups per day. The results for cancer mortality suggest the absence of an effect over the range of consumption up to 8 cups per day.

THE BAD SIDE OF COFFEE

Excessive intake of caffeine has been associated with anxiety, headaches, nausea, hypertension and restlessness but there is significant individual variation as to susceptibility and the amount required to produce these adverse effects. Caffeine is also well known to be addictive with significant withdrawal symptoms such as headache, lethargy and irritability when consumption is abruptly stopped.

ROLE OF THE MODE OF PREPARATION

The liquid in the coffee cup is in fact a complex mixture with over 1000 chemical compounds already identified and some of their biological effects characterized. The amounts vary depending, on the bean roasting and drying process, the coffee varieties being blended and the technique of brewing. The degree of roasting for example impacts the level of antioxidants. Cholesterol, triglyceride, and homocysteine-rising chemicals are found in unfiltered coffee such as Turkish coffee and boiled coffee, but are mostly absorbed by the filter. The studies discussed above do not take into account any of the factors associated with the mode of preparation. However, elevated levels of chemicals thought to enhance risk appear to be balanced out by beneficial effects since overall, coffee appears to present either a neutral risk profile or evidence of benefit.[6]

THE BOTTOM LINE

Historically, coffee consumption in excess was viewed as bad for one's health. This view has been displaced by many recent studies which suggest a likely significant beneficial impact of consumption of this popular beverage. No disease risk appears to have been identified. Thus until this picture changes, readers can enjoy their coffee and even high consumption without concern for adverse consequences and can in fact anticipate some benefit over and above stimulation and the social aspects of the activity.

AUTISM AND ACETAMINOPHEN USE. IS THERE A CONNECTION?

It has been estimated that the prevalence in the US of autism prior to 1980 was approximately 1 per 2500 children and now we are at about 1 per 68. It is a good guess that the next number issued by the CDC will be around 50. The obvious question is why the huge increase? While a number of hypotheses have been advanced, this issue is controversial.[7]

A decade ago the suggestion of an association between fever suppression and underlying biological mechanisms of the development of autism (etiology) was suggested.[8] The circumstantial evidence linking acetaminophen (Tylenol) and autism has been growing since then and is thus of considerable interest. Consider the following:[8]

- If one graphs the number of autism cases by birth year registered with the California Development Services for those born between the years 1963 and 1978 it is almost constant at around 150. In 1980 there is a sharp departure with registrations increasing exponentially. The published graph stops at the birth year 1990 at which time the registrations numbered 600. In 1980 the public was warned of the association of aspirin and risk of Reyes's syndrome which cause a sudden switch to acetaminophen.
- After 1980, acetaminophen essentially replaced aspirin in the primary treatment of fever in children and pregnant women.
- The graph shows two breaks in the exponential rise, both associated with scares due to tampered acetaminophen associated with attempted terrorism or murder which caused an immediate but short duration drop in acetaminophen consumption.
- In 1982, acetaminophen sales were approximately $400 million. In 2008 the number is about $2,600 million.
- Autistic children have a decreased metabolic capacity associated with a defect in the acetaminophen metabolism process. In the case of children who are poor metabolizers of acetaminophen, normal therapeutic doses could lead to abnormal blood levels.[9]
- Acetaminophen has recently been shown to be associated with genetic changes in gene expression related to immune modulation and oxidative stress even at low doses. Both are strongly implicated in autism.
- In a study published in 2008 it was found that the use of acetaminophen after the MMR vaccination increased dramatically the risk of autism. The immediate side effects of the MMR vaccination can produce symptoms that are frequently treated with acetaminophen. There was no association with post vaccination use of Ibuprofen. There were no subjects that used aspirin.[10]
- A recent study found that children exposed to long-term use of acetaminophen during gestation had adverse neurodevelopmental outcomes at 3 years of age. However, only

some aspects of the autism spectrum disorder were evident and the authors did not conclude that this subgroup had autism.[11]

- It has been suggested that the use of acetaminophen may trigger autism by activating what is called the endocannabinoid system and thus interfering with normal development.
- Based on human studies there is an overlap in genetic susceptibility, molecular pathways, and other features with early preclinical etiological events shared by autism and asthma. There is also strong evidence from human studies that acetaminophen use late in pregnancy or by children in the first year of life increases the risk of subsequently acquiring childhood asthma and related allergic disorders.[12]

If one examines online the FDA approved package insert for acetaminophen, one finds no mention of this potential risk of autism. This is also true with the popular websites providing health information in this context. Evidentially, the evidence presented above is so insignificant in the estimation of evidence-based medicine that this possibility does not merit serious consideration, which is not surprising.

EVER HEARD OF THE VACCINE COURT?

The current war of words in the network and social media of the so-called measles epidemic over the past month or so has been one of the strongest in the history of the debate over vaccination. The pro-vaccines advocates champion the official position that vaccines are safe, cause negligible harm and accuse those who resist, the anti-vaxers, as endangering public health, a notion based on the herd effect, which should properly be called the herd hypothesis. It is coming under increasing critical scrutiny.

It is not the purpose here to discuss these issues but rather to attempt to gain some insight into the risk aspect by examining the data available in the public records from the so-called *Vaccine Court*, which is actually named the Office of Special Master of the US Court of Federal Claims. This court came into existence when the U.S Department of Health and Human Services set up the National Vaccine Injury Compensation Program in 1988 to compensate individuals and families injured by a specific set of vaccines. Claims against vaccine manufacturers cannot be heard in state or federal civil courts, something that appears unique. The vaccine manufacturers have been guaranteed total indemnity and successful claims in the Vaccine Court are paid by the U.S. government, partly through a surcharge on prescriptions. Those advancing a claim are not liable for legal expenses, their own or the government's, independent of success or failure. The U.S. government pays the total bill. The Vaccine Court does not allow a jury. Decisions are made by individual so-called masters. The Vaccine Court also appears unique.

Vaccines are thus a special case since medical malpractice lawsuits are of course common in the U.S and some law firms advertise that "you don't pay unless we win," called taking cases on contingency. A study by Tehrani *et al* published in 2013 provides data for the normal civil court U.S. malpractice claim success over 25 years up to 2010.[13] Likewise the public records of the Vaccine Court provide similar data over 25 years up to 2014 (ignoring the small contribution from 2015 which is of course incomplete) which can be found on the internet. Some interesting data is thus available.

In the recent 25-year period in the US, medical malpractice awards totaled about $110 billion of which $4.8 billion were medication related.[13] There were about 18700 claims concerning

medication out of a total of about 350,700 total claims. In the Vaccine Court for roughly the same period, where the issue is also medication, $2.9 billion was awarded with an additional $122 million in legal fees and costs paid. There were a total of 3981 successful claims over this period. It is of course understood that this comparison is approximate since medication claims in malpractice lawsuits cover a broader area than those alleged to involve injury or death from vaccines. Nevertheless, the average payout per successful claim in Vaccine Court was higher than awarded in regular civil court cases. Compensation in Vaccine Court covers medical and legal expenses, loss of future earning capacity, and a lump sum for pain and suffering as well as a death benefit. However, there are no avenues of litigation for the financial losses and emotional damage parents suffer.

Since the spectrum of vaccines has changed over the years, in particular the replacement of DTP, it is instructive to examine the data provided by the Vaccine Court for the period 2006 to date for the success or failure of claims for the vaccines that appear most frequently in the data. The data are summarized in the table given below.

TABLE. Cases and results for five vaccines most commonly involved in claims. Period 2006 to present.

Vaccine	Doses 2006-13	Total	Compensated	Failed	Compensated claim per million doses
All	2,236,678,735	2853	1672	1181	0.8
DTaP	75,888,233	182	105	77	1.4
Hep-B	129,820,136	88	52	36	0.4
HPV	67,250,574	160	74	80	1.1
FLU	994,000,000	1144	970	174	0.1
MMR	73,441,576	158	86	72	1.2

The last column suggests that the risk for harm associated with a single dose of either any or one of the designated vaccines as measured by a successful claim in court is of the order of one in a million. However, when there is harm, it can be catastrophic for all concerned. What one does not know is the fraction of cases of alleged harm that actually go to court or even the number of parents aware of both the Vaccine Court or the absence of court and attorney fees provided the petition is accepted. Thus the numbers in this table only indicate that significant harm can occur as judged by court adjudication as due more likely as not to the vaccination, the preponderance of evidence standard. Each vaccine has its own time limits, and many other restrictions are associated with making a petition.

The above numbers may lead to a more rational view of this subject, although it is severely limited by lack of knowledge of petitions to make a claim that should have been allowed but were refused, and how many with valid cases never pursued this option. This is a complex issue since there is a high level of denial among health care professionals and a strong tendency to explain the alleged harm as a coincidence unrelated to the vaccination, and there is an absence of data needed to resolving this difference in views.

For an in-depth look at the Vaccine Court, read Wayne Rohde's book *Vaccine Court. The dark truth of America's vaccine injury compensation program,* published in 2014. Throughout the book he discusses problems associated not only with the original bill passed in 1986 but also changes that have occurred since then. All parties involved appear to agree that reform is necessary. Problems with the court are clear from the summary he gives of thirteen reforms in

chapter 14 that have been or are being discussed. Evidence is presented that many aspects of this compensation program design and operation unfairly favor the government, tend to intentionally limit both the number of successful petitions and those that succeed in obtaining compensation, and do not even meet the intent of the US congress when it passed the bill setting up the court.

What seems clear from Rohde's carefully researched book is that the numbers on the court website underestimate the number of individuals with claims likely to be valid, the compensation provided can be unrealistic, the time to decision so long (4-10 years) that it can produce severe hardship. In addition, there appears to be an intentional absence of transparency, the process is highly adversarial, and many individuals and families that might qualify to file a petition are unaware of the existence of the court. It is important to understand that in many of these cases we have parents experiencing a financial and emotional disaster up against the combined power of the Department of Justice and the Department of Human Health Services. To gain perspective, read the summaries at the end of Chapter 14.

THE BOTTOM LINE

Success in Vaccine Court is not proof that the vaccination caused harm, only a preponderance of evidence in favor of this view. Furthermore, we will never know the true risk. Measured by the probability of a successful claim yielded roughly one in a million doses based on the data in the Table. But what if it is really one in ten thousand, i.e. the case numbers underestimate the real prevalence by a factor of 100? Given the culture of almost total denial of the possibility of injury, the position that it is genetic and would have happened anyway, or the "it is simply a coincidence" arguments from trusted professionals, all of which discourage pursuing the injury hypothesis, such an underestimate may not be too farfetched. The whole subject we have been discussing seems characterized by a playing field that is far from level.

NEWS BRIEFS

BE PREPARED FOR PRESSURE TO GET A PNEUMONIA VACCINATION

In the February 17 issue of the *JAMA* both a clinical guideline synopsis and a "patient page" provided arguments in favor of mass vaccination for pneumonia by targeting *Streptococcus pneumonia* also called *Pneumococcal Pneumonia.* The guidelines apply to all individuals over 65 years of age and involve the addition of a new vaccine (PCV13) to the existing vaccine (PPSV23). When these guidelines came out, the placebo controlled randomized trial of the PCV13 vaccine had not been published, but there were preliminary relative risk results. For individuals who have never had the PPSV23 vaccination, both were recommended with a dosing schedule. For those who had been vaccinated, adding the new vaccination was recommended with a schedule depending on when the older vaccine had been given. Central to the recommendation was the finding in the unpublished trial (CAPITA) that the vaccine efficacy for PVC13 for preventing the first episode of community acquired pneumonia from the above bacterium was 45.56%, a relative risk reduction (note the absurd number of significant figures).[14] In the patient page paper, it was further recommended that all children under 5 should get the PCV13 vaccination, but unless there was significant risk, it was not indicated for those between 19 and 65.[15]

Now the CAPITA trial results have been published.[16] It applies only to those over 65. No children were included. The vaccinated and placebo groups each contained about 42,000 individuals. The most important results are shown in a figure of cumulative first episodes over about 4.5 years. In the placebo group and the vaccinated group there were 90 and 48 events,

respectively. Thus the absolute risk reduction for this type of community-acquired pneumonia was 42 per 42,200 individuals giving a number needed to vaccinate of about 1000 to prevent one case. In terms of percentages, 99.9% were out of luck. When there is negligible benefit, one turns to risk of side effects. This was a trial carried out by the vaccine maker and most of the authors of the report had strong ties with the company or work for it. Thus, given the history of such studies, one must look with suspicion on the statements regarding no vaccine-related serious adverse effects were observed.

If it is indeed true that less than 1 in 1000 experienced a serious vaccine related side effects, then mass vaccination in large populations would, on balance, produce more benefit than that risk, but unfortunately the benefit by at least some standards, is negligible.

THE BOTTOM LINE

45.56% efficacy and benefit to only one in 1000 is a good example of the deception associated with relative risk reduction numbers. The latter are used to sell patients on numerous drugs, frequently for life. Statins are the prime example. In the above example, the benefit is very small, and critics could say the risks of side effects are unknown. There does not appear to be any studies comparing the recommended combined vaccine protocol with a placebo, nor are there studies on children under 5. It might require vaccinating several hundred thousand children and keeping track of an equal number of controls to get statistically significant results, given that the CAPITA trial involved participants with a mean age of about 72, an age group with elevated risk of pneumonia compared to the general population. The cumulative incidence was only at 2 cases per 1000 in the placebo group. However, the recommendation is consistent with modern practice where drugs or therapies are used on children when off-label and totally untested in randomized controlled trials or generally any trials at all.

AUTISM AND INFANT AND TODDLER GUT PROBLEMS

A large prospective (follow-up) study has just reported that found maternally reported gastrointestinal symptoms (constipation, diarrhea, food sensitivities) were more common and often more persistent during the first 3 years of life in children with the autism spectrum disorder than in children with typical development or delayed development.[17] However, this has been common knowledge for over a decade among open-minded physicians who treat autistic children and has been discussed several times in IHN (see new index). Readers are referred to *Gut and Psychology Syndrome* by Natasha Campbell-McBride MD, *Children with Starving Brains* by Jacquelyn McCandless MD, and *The Autism Revolution* by Martha Herbert MD, the latest book in this area written by a Harvard pediatric neurologist. The only thing one needs to say about the study is that it will make those who demand more than extensive anecdotal evidence more likely to consider this possibility. Whether it will lead to a more widespread appreciation of the necessity of a whole-body approach to treating autism is unknown. Your editor is reminded of the classic comment of a psychiatrist to a mother when told about serious problems with chronic constipation as an initial sign of her child's autism. She was told, "Madam, I am a psychiatrist, not a gastroenterologist and your child's problem is in the brain."

Anyone interested in autism and in particular the autism-gut connection is strongly encouraged to read Chapters 2 and 5 in McCandless' book and Chapter 4 in Herbert's book. Note that Herbert's book carries the imprimatur of Harvard Health Publications—Harvard Medical School and is quite recent.

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