

DIETARY SALT AND HEALTH, 2000-2009

Richard L. Hanneman

Salt Institute

Keywords: dietary salt reduction, diet, health, outcomes, recommendations

Executive summary

For decades, public health nutrition policymakers have been asking the wrong question in the ongoing debate over whether reducing population salt intake would improve public health. From the outset, the question has been framed in terms of blood pressure. Solid evidence shows that populations with higher average blood pressures have significantly more heart attacks and strokes. Other quality studies demonstrate that significant reductions in salt intake can modestly reduce average population blood pressure, though the effect varies widely. Epidemiologists have argued for decades whether it is valid, on the basis of projected blood pressure lowering through salt reduction to extrapolate the cardiovascular benefits of populations with lower average blood pressures.

This was always the wrong question. Medical scientists now well understand that reducing dietary salt intakes triggers disparate metabolic changes, many that have cardiovascular risks exactly the opposite of that predicted for salt reduction. It was not until 15 years ago that medical scientists began to ask and answer the right question: would salt reduction improve health outcomes? Incidence of heart attacks and cardiovascular mortality are the consensus objective, but the link had never been tested directly.

It has now, but, until 2008, only in observational studies, not randomized controlled trials. Those observational health outcomes studies, however, taken together, have not confirmed the theoretical benefit in reducing population salt intakes; in fact, several have identified potential risks. Last year, Italian scientists published the first-ever randomized controlled health outcomes trial comparing congestive heart failure patients who consumed normal salt intakes with those treated with reduced salt diets. The low-salt dieters fared far worse. The results should motivate public health agencies to fund a definitive study in the healthy population which may confirm that three decades of trying to reduce population salt intakes was not only wrong, but dangerous.

Science is a process of creating, testing and revising hypotheses. Properly done, it evolves, throwing more and more light on a problem and illuminating our understanding. With dietary salt, however, the process has been manipulated by proponents of universal salt reduction, producing sparks of controversy and more heat than light. An award-winning analysis described "the (political) science of salt."

The Salt Institute has tried to inject science, and, specifically, the need for answers to the "right question." The lessons learned since the last Salt Symposium offer insights into how this

important public health nutrition question might be resolved to curtail the “politics” and bring greater alignment of science with population dietary advice.

Introduction

Fifteen years ago, M. Neil Browne and Stuart M. Keeley wrote *Asking the Right Questions: A Guide to Critical Thinking*.⁴² Clearly, intelligent inquiry peels back layers of ignorance helping us to discover eternal truths. Thinking is the process of questioning and the key is to ask the right questions in order to get the right answers. Asking the wrong question is like taking the wrong road; no matter how far and how fast we travel, if we are headed in the wrong direction, we will not reach our intended destination.

Failing to ask the right question about dietary salt intakes and health consequences has put us on the wrong road. Anxious to reach our goal of improved health, many health nutrition agencies have put “the pedal to the metal” with more strident rhetoric and drastic attempts to re-engineer our food supplies. But they are on the wrong road and will be disappointed at the destination when they arrive.

In nearly a full decade since Salt 2000, the sound and the fury surrounding the public health concern for overall population dietary salt intake levels has accelerated. Proponents of universal salt reduction have turned up the heat.

Coincidentally, significant advances in medical scholarship have shed new light on this relationship.

To understand how this issue has played out over the past decade, we need to look at:

- How science has been controlled and manipulated
- How salt reduction activists have “myth-informed” the public
- Actual advances in scientific understanding of salt and health

- How we can move into the future with better hope to align science and policy

The strategies employed by salt reduction activists during this period, unfortunately, generate more heat than light and as a consequence insight. More extreme warnings and attempts to reduce the salt intake of individual foods represent a retreat from sound science and create a growing gulf between what scientists know to be true and what these public health agencies are trying to promote by way of population salt reduction.

We need to understand the misleading strategies and tactics of these activists and what current, quality science can teach us. This understanding can help get us back on the road to using diet to improve health. It will end the detour we’ve taken following erroneous directions we have received through deceitful scientific abuse and cynical exploitation of popular (and media) ignorance of the standards of scientific inquiry. Salt Institute technical director Morton Satin terms this, “myth-information.”⁴³ And understanding these tactics will help us defeat them and set the stage to expand further scientific understanding of the important role of salt and health.

All of this misdirection and lost time has been due to our failure to ask the right question before proceeding to recommend universal salt reduction. There are actually two “right questions” to answer: Will lowering intakes of dietary salt improve health outcomes? And, if so, will reducing the salt content of individual foods achieve lower overall sodium intake levels? A “no” answer to either question will put us back on the road to truth.

Deceitful scientific abuse and cynical exploitation of scientific ignorance

The Golden Rule: He who has the gold, rules.

⁴² M. Neil Browne and Stuart M. Keeley. *Asking the Right Questions: A Guide to Critical Thinking*. Prentice-Hall, ISBN 0130493953 / 9780130493958 / 0-13-049395-3

⁴³ Morton Satin, *Salt Diet and Health* (<http://www.saltinstitute.org/content/download/926/4962>)

In the U.S. and many other countries, enormous allocations of health research dollars have explored every nook and cranny of the relationship of dietary salt and high blood pressure, hypertension. The research stretches back a half century, motivated by the long-understood fact that salt is implicated in blood pressure (the "salt hypothesis") and persuasive 20th Century research establishing that populations with lower average (systolic) blood pressure have significantly lower rates of cardiovascular (CV) events (heart attacks and strokes) and cardiovascular mortality. With a plausible mechanism and hopeful extrapolations of massive benefits in reduced mortality and health care costs, governments pumped billions of dollars into salt-related research over the past quarter-century.

The National Heart, Lung and Blood Institute (NHLBI) funded much of the research exploring the salt hypothesis. Early on, NHLBI became a cheerleader, not an honest broker. With its active encouragement, official U.S. policy, established in the Dietary Guidelines for Americans beginning in 1980,⁴⁴ became to reduce (or "moderate") population salt intake levels with the expectation that this was both achievable and would result in reducing average blood pressure which, in turn, would realize improved health outcomes. From the beginning, the debate was framed in terms of blood pressure and focused projections of improved health outcomes.

Much later, other countries and the World Health Organization⁴⁵ marched down this same pathway.

⁴⁴ US Department of Agriculture. History of Dietary Guidelines for Americans (<http://www.health.gov/dietaryguidelines/dga95/12DIETAP.HTM>, accessed April 22, 2009). Answers.com "Dietary Guidelines" (<http://www.answers.com/topic/dietary-guidelines>, accessed April 22, 2009)

⁴⁵ World Health Organization, Diet, Nutrition and the Prevention of Chronic Diseases. WHO Technical Report Series 916 (2003) (http://whqlibdoc.who.int/trs/who_TRS_916.pdf)

Investigative reporter Gary Taubes addressed the situation in his 1998 exposé in the prestigious journal, *Science*, "The (Political) Science of Salt"⁴⁶ for which he won the national award of the U.S. Science Writers Association.⁴⁷ Taubes uncovered an unsavory pattern of scientific manipulation and abuse, including relationships between NHLBI and their favorite researchers. Some research institutions, such as Johns Hopkins University, rely heavily on NHLBI funding and NHLBI can rely just as heavily on their research teams dependably reporting policy-favorable research findings. NHLBI has bestowed tens of millions of American tax dollars on favored researchers to pursue NHLBI's research agenda in promoting salt reduction.

Somehow, doubting scientists scraped together funding for studies that challenged the comfortable assumptions portrayed by NHLBI, but they lacked the resources to conduct the definitive controlled trial of health outcomes of salt-reduced diets.⁴⁸ Appeals by the Salt Institute, joined by the presidents of the American Society of Hypertension and the International Society of Hypertension were greeted with the response that the industry should pay for the study if it felt it was worthwhile; the feds did not.

⁴⁶ Gary Taubes, The (Political) Science of Salt, *Science*, August 14, 1998; Vol. 281. no. 5379, pp. 898 - 907 (<http://www.sciencemag.org/cgi/content/short/281/5379/898>)

⁴⁷ <http://www.nasw.org/awards/1999/index.htm> (accessed April 22, 2009)

⁴⁸ The proposed study would be modeled on two trials already funded by NHLBI: the ALLHAT health outcomes study of anti-hypertensive drugs (The Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial, <http://allhat.sph.uth.tmc.edu/>) and the dietary sodium TOHP II study (NHLBI, Trials of Hypertension Prevention, phases I and II, <http://www.nhlbi.nih.gov/resources/deca/descriptions/tohp.htm>). That study remains unfunded.

Not content with NHLBI's starvation diet for dissenters, more extreme salt reduction activists employ torture, questioning the character of politically-incorrect scientists. The sad truth is that researchers convinced that the evidence does not support universal salt reduction are still mightily concerned with combating cardiovascular disease. It's just that they've started looking in other areas for their answers, leaving the field to those die-hard anti-salt researchers for whom proving the guilt of salt has become the holy grail of their professional existence.

To inform itself, the Salt Institute consults with prominent experts to make sure its statements credibly track the science. Our public statements for the past 13 years are posted on our website for all to see.⁴⁹ We value the counsel we receive. Most often, our advisors donate their consulting services since even to accept a couple thousand dollar honorarium invites brutal personal attacks on their reputation as independent scientists – attacks often leveled by peers who see no conflict in taking millions of dollars from government agencies anxious to document their policy choices. We are proud of our advisors for their courage as well as their expertise and wisdom.

This is part of an unhealthy general attack on industry-funded science⁵⁰ intended to create

⁴⁹<http://www.saltinstitute.org/News-events-media/Releases-statements>

50 Examples include: Ronald Bailey, "Is Industry-Funded Science Killing You?" Reason, October 2007 (<http://www.reason.com/news/show/122020.html>); "Industry-funded organizations," Sourcewatch (http://www.sourcewatch.org/index.php?title=Industry-funded_organizations); "Scrutinizing Industry-Funded Science: The Crusade Against Conflicts of Interest," American Council on Science and Health (http://www.acsh.org/publications/pubID.1687/pub_detail.asp); Sandy Szwarc "Do you know where your health news and information comes from? Junk Food Science, November 25, 2008 (<http://junkfoodscience.blogspot.com/2008/11/do-you-know-where-your-health-news-and.html>).

a government monopoly on information available to inform public discourse. We need to keep our focus on the quality of the science, being mindful that whoever is footing the bill for research doubtless has a stake in the outcome.

Misrepresenting science

While NHLBI wields its purse in selecting reliable researchers, the researchers hold up their end of the bargain by selectively reporting their data.

The case of the two Dietary Approaches to Stop Hypertension (DASH) trials illustrate. In 1997, the original Dietary Approaches to Stop Hypertension (DASH) study was reported.⁵¹ It electrified the salt and health community by finding massive blood pressure-lowering effects of a diet rich in fruits, vegetables and dairy products – but without manipulating salt intakes. Up to that time, NHLBI had insisted all the trials it funded include salt-reduction as part of every intervention because "everyone knew" salt reduction was beneficial and, arguably, if so, it would be unethical not to have subjects get this benefit. DASH held salt constant. The results: for the most sensitive group, hypertensives, a "DASH Diet" lowered systolic blood pressure (SBP) by 11.4 mmHg, an impressive reduction.

The Salt Institute exulted at this high-quality, though short-term study (only 30-days).⁵² We proclaimed vindication of our advocacy of a total diet focus recommendation. NHLBI set to work to "refine" the finding by authorizing a second "DASH" study, this time to lower salt with the presumed outcome of adding this second intervention to enhance the DASH Diet's blood pressure lowering effect. Indeed it did. When this

51 Lawrence J. Appel et al. A Clinical Trial of the Effects of Dietary Patterns on Blood Pressure. New England Journal of Medicine, April 17, 1997; 336:1117-1124 (<http://content.nejm.org/cgi/content/abstract/336/16/1117>).

52 Richard L. Hanneman statement on DASH diet (<http://www.saltinstitute.org/content/download/1067/6200>).

DASH-Sodium trial was published,⁵³ it claimed hypertensives who followed the DASH Diet, but also reduced their salt intake by 60% lowered their SBP by 11.5 mmHg. The Salt Institute argued that virtually the entire "benefit" was attributable to the DASH Diet since the blood pressure difference in the most sensitive (hypertensive) group was only 0.1 mmHg was due to salt and 11.4 mmHg to the DASH Diet. We interpret the study as confirming the central importance of a quality (DASH) diet. NHLBI, meanwhile, trumpeted that the results as confirmed that "every American" would benefit by salt reduction: "Now we can say that cutting back on dietary sodium will benefit Americans generally and not just those with high blood pressure."⁵⁴ The NHLBI team clearly emphasized an impact for salt that its contract researchers showed was far outweighed by the "quality" DASH Diet.⁵⁵

A few years later, when the DASH-Sodium study was being used to encourage tougher anti-salt language in the 2005 Dietary Guidelines, the DASH team published a subgroup analysis authored by George Bray⁵⁶

which conceded that there was no statistically-significant relationship in six of the eight subgroups examined (inexplicably the overweight group analysis was omitted). Those subgroups represented better than 80% of the U.S. population. Yet co-author Dr. Lawrence Appel, a member of the Dietary Guidelines Advisory Committee, portrayed the findings as further confirmation of the original hypothesis that the reduced-salt group achieved better blood pressures.

There has been a consistent pattern of misrepresenting the data.

NHLBI also misrepresented the 1988 Intersalt Study.^{57,58} The primary hypothesis of that study was that populations with lower salt intakes (as registered by 24-hour urinary analysis) would have lower SBP. The data showed no relationship. So NHLBI claimed that the true meaning of the data could be understood by analyzing for "slope with age" which they claimed showed high-salt populations developing hypertension as they aged. They ignored the genetics of the Yanomamo tribe which is genetically shielded from age-related blood pressure increases – no matter how much salt they consume.⁵⁹ The Salt Institute sought a couple simple

53 Frank M. Sacks, et al, "Effects on Blood Pressure of Reduced Dietary Sodium and the Dietary Approaches to Stop Hypertension (DASH) Diet." *New England Journal of Medicine*, January 4, 2001; 344:3-10 (<http://content.nejm.org/cgi/content/abstract/344/1/3>).

54 National Institutes of Health news release, "Reducing Sodium Leads to Substantial Drop in Blood Pressure, Finds NHLBI Study" January 3, 2001. (<http://www.nhlbi.nih.gov/new/press/01-01-03.htm>).

55 National Institutes of Health news release, "NHLBI Study Shows Large Blood Pressure Benefit From Reduced Dietary Sodium." May 17, 2000 (<http://www.nhlbi.nih.gov/new/press/may17-00.htm>).

56 G.A. Bray, et al. "A further subgroup analysis of the effects of the DASH diet and three dietary sodium levels on blood pressure: results of the DASH-Sodium Trial." *American Journal of Cardiology*, July 15, 2004; 94(2):222-7.

(<http://www.ncbi.nlm.nih.gov/pubmed/15246908?dopt=Abstract>).

57 Intersalt Cooperative Research Group. "Intersalt: an international study of electrolyte excretion and blood pressure. Results for 24 hour urinary sodium and potassium excretion.: *British Medical Journal (BMJ)*, July 30, 1988: BMJ 1988;297:319-328 (<http://www.bmj.com/cgi/content/abstract/297/6644/319>).

58 David A Freeman and Diana B Petitti. "Salt, blood pressure and public policy." *International Journal of Epidemiology* 2002;31:319-320 (<http://ije.oxfordjournals.org/cgi/content/full/31/2/319>).

59 Morton Satin, "The Yanomamo Myth," Salt Sensibility Blog (Salt Institute), May 21, 2008. (<http://www.saltinstitute.org/News-events-media/Salt-Sensibility/Health/The-Yanomamo-Myth>).

statistics: starting blood pressure chief among them. It took until 1994 to extract that simple statistic which showed that populations with a lower "slope" started with higher blood pressures.⁶⁰

These are typical, but hardly the only examples of purposeful misstatements of the evidence. More recent examples are the World Health Organization's Report 916,⁶¹ the European Union's diet and obesity "platform,"⁶² a compendium of error-filled allegations developed by the activist group Center for Science in the Public Interest,⁶³ attributions of health improvements due to salt reduction in Finland⁶⁴ and fraudulent claims of salt reduction by the British Food Standards Agency.⁶⁵ And other groups are caught up repeating the falsehoods (e.g. the

American Public Health Association^{66,67} and American Medical Association which both used the distorted "findings" to justify loud calls for salt reduction).

Beyond misstating the science, salt reduction activists also routinely misstate objections to their advocacy. In my debate before the Royal Society of Chemistry in London, I was shocked when Dr. Graham MacGregor pronounced himself pleased that in my remarks I had conceded the bedrock fact that salt and blood pressure are related – a complete straw man. Likewise, the Salt Institute's advocacy on reduced salt diets has been carefully limited to the public health issue – population advice on salt intakes. Doctors and other medical professionals prescribing low-salt dietary therapy may be right or may be wrong – but their advice is beyond the scope of our advocacy concerning dietary salt.

Dire warnings, draconian interventions

60 Richard L. Hanneman. "Intersalt: hypertension rise with age revisited." *British Medical Journal (BMJ)* May 18, 1996; 312:1283-1284 (<http://www.bmj.com/cgi/content/short/312/7041/1283>).

61 Op cit. footnote 4.

62 European Union. "EU Platform For Action On Diet, Physical Activity And Health," March 15, 2005 (http://ec.europa.eu/health/ph_determinants/life_style/nutrition/platform/docs/platform_character.pdf)

63 Center for Science in the Public Interest (CSPI), "Salt: The Forgotten Killer." 2005. (http://cspinet.org/new/pdf/salt_report_with_cover.pdf)

64 Morton Satin. "Health outcomes lessons from Finland's salt reduction." *Salt and Health newsletter* (Salt Institute), Summer, 2007 (<http://www.saltinstitute.org/content/download/259/1487>).

65 Richard L. Hanneman, "FSA anti-salt 'progress' is a dangerous charade." *Salt Sensibility Blog* (Salt Institute), November 7, 2008 (<http://www.saltinstitute.org/News-events-media/Salt-Sensibility/Health/FSA-anti-salt-progress-is-a-dangerous-charade>).

66 American Public Health Association. *Policy Statement: Reducing Sodium Content in the American Diet.* November 13, 2002 (<http://www.apha.org/advocacy/policy/policysearch/default.htm?id=278>).

67 Richard L. Hanneman. "Salt Institute reaction statement to American Public Health Association's call for 50% salt reduction over 10 years." November 12, 2002. (<http://www.saltinstitute.org/content/download/820/4530>).

Perhaps influenced by misreporting, perhaps reflecting the government's underlying bias favoring universal salt reduction, the U.S. Dietary Guidelines are now 30 years old. Salt reduction was included from the outset, the first iteration of the Dietary Guidelines for Americans in 1980 recommending that Americans consume "moderate" amounts of sodium.⁶⁸

Americans have failed to reduce their salt intake level; in fact, salt intakes are unchanged over the past century. When research clarified public resistance, salt reduction activists resorted to increasingly shrill promotion of progressively extreme policy interventions. With successive iterations of the quintennial Dietary Guidelines, the Guidelines' language became more extreme even as the science failed to provide a rationale for tightening. The Guidelines "crossed the line" in 2000 when, for the first time, they specifically advised Americans to "eat less" salt. Before that time, reasonable scientists could agree on "moderate" salt consumption though they might quarrel over what amount would be considered "moderate." For the first time, the Salt Institute refused to endorse the 2000 Guidelines, declaring:

In the past five years since the salt/sodium guideline was established to "choose a diet moderate in salt and sodium," the evidence

⁶⁸ Reducing population salt intakes has been a roiling debate in the U.S. since that era, but Americans were quickly propagandized to dread salt's health consequences. From the outset, more extreme activists such as the Center for Science in the Public Interest (CSPI) argued that the voluntary guidelines would never work since people could not be relied upon to accept the importance of salt reduction and make the changes in food choices to lower overall sodium intakes. CSPI called for repeal of salt's GRAS status (the Food and Drug Administration does not regulate salt consumption owing to its longstanding history of safe use in foods, hence salt is the first-named among substances accorded the status "Generally Recognized as Safe.") (CSPI, <http://www.cspinet.org/new/200711271.html>, accessed April 22, 2009)

has continued to mount that this is mistaken advice based on a misreading of the science. Yet this recommendation actually moves in the exact opposite direction; the proposal would encourage all Americans to eat less salt, not consume salt in moderate amounts. Science does not support this recommendation, nor give us confidence that sodium reduction is beneficial for cardiovascular health.⁶⁹

In 2005, the Guidelines went a step further and specified a numeric target, 2,300 mg/day sodium (even as the Guideline talked about "salt"). The increased stridency of the advisory and the specificity of the advice suggested to the public an advancing scientific understanding of adverse consequences of current levels of salt consumption – clearly a conclusion bred of frustration in lack of compliance more than advancing science.

Activists stirred the pot. The American Public Health Association in 2002 urged restaurants to halve the amount of salt in their foods.⁷⁰ In November 2005, CSPI petitioned the Food and Drug Administration (again) seeking repeal of salt's GRAS status.⁷¹ In June 2006, the American Medical Association asked food manufacturers and restaurants for a two-thirds salt cut, echoing the CSPI claim that this would save 150,000 American lives each year.^{72,73}

⁶⁹ Richard L. Hanneman letter to HHS Secretary Donna Shalala and USDA Secretary Dan Glickman, March 15, 2000 (<http://www.saltinstitute.org/content/download/862/4698>).

⁷⁰ Op. cit. foodnote 25.

⁷¹ CSPI petition to HHS, November 8, 2005 (http://www.cspinet.org/salt/fda_salt_petition.pdf).

⁷² American Medical Association. Directives of the House of Delegates, page 51 (<http://www.ama-assn.org/ad-com/polfind/Directives.pdf>).

⁷³ Barry D. Dickinson and Stephen Havas, "Reducing the Population Burden

With increasing consistency, salt reduction activists now tacitly concede that consumer education will never achieve the desired salt reductions, condemning the popular taste for salt and disparaging the notion of a "salt appetite." In turn, refusing to accept a physiologic mechanism has led salt reduction activists to a deepening frustration as Americans resist the constant drumbeat of their salt-demonizing public relations barrage. This frustration, in turn, has produced recruits for the strategy recommended by CSPI back in the 1970s: to portray consumers as victims of the food industry and unable to make healthy dietary choices. That strategy had been rejected as too radical, but less draconian encouragement and propagandizing have proved utterly ineffective. Government, the more extreme activists have concluded, must step in and force industry to re-engineer the food supply to lower the sodium content of individual foods. They fail to question their basic premise: that food choices determine total sodium intake. Their solution of setting per-serving sodium targets, of course, says nothing about how many servings consumers will choose. No research has examined the efficacy of this strategy (or contested the physiology research about sodium appetite⁷⁴ that suggests this approach is doomed).

An American lawyer's primer instructs that when you don't have the facts on your side,

of Cardiovascular Disease by Reducing Sodium Intake." Archives of Internal Medicine, July 23, 2007;167(14):1460-1468 (<http://archinte.ama-assn.org/cgi/content/abstract/167/14/1460>).

74 Joel C. Geerling and Arthur D. Loewy. "Sodium depletion activates the aldosterone-sensitive neurons in the NTS independently of thirst." American Journal of Physiology Regulatory, Integrative and Comparative Physiology, March 2007;292, R1338-R1348 (<http://ajpregu.physiology.org/cgi/reprint/292/3/R1338>), and Geerling and Loewy, "Central Regulation of Sodium Appetite," Experimental Physiology, February 2008; 93:165-176 (<http://ep.physoc.org/content/93/2/177.full.pdf+html>).

argue the law. When you don't have the law on your side, argue the facts. When you have neither facts nor law on your side, argue louder." In short, substitute heat for light if the light would illuminate something you are trying to hide.

Hiding the data

NHLBI employs lawyers as well as doctors. The first advice lawyers press on arrested subjects is "stop talking" since "the things you say may be used against you in a court of law." A defense in court is less credible when undermined by an earlier confession of incriminating facts. That advice guides the duopoly of NHLBI and its contract researchers. The agency has established a clear pattern of trying to shore up the credibility of its salt-denigrating pronouncements by denying public access to "inconvenient" data in studies it funds that fail to support its statements.

Our six-year effort to extract some statistical data from the Intersalt Study illustrates the pattern. Worse is our experience with the second DASH study, the DASH-Sodium study. Our quest for independent review of the DASH-Sodium statistics is still ongoing, making it even longer than the struggle to free the Intersalt data.

Without revisiting all the particulars, suffice it to note that we feel that the DASH-Sodium data will likely show no blood pressure benefit for the population from either the 2,300 mg/day "recommended" sodium intake level or the 1,500 mg/day, 60% reduced level in the test. Four simple statistics, already surely calculated in the original analysis, are being withheld. From the outset, we sought these simple statistics and were rebuffed.

Since the study, like Intersalt, was federally-funded, we considered seeking release of the data under the Freedom of Information Act (FOIA). We had tried that route with the Intersalt data and learned that the federal bureaucracy can avoid FOIA by "contracting" with their client researchers rather than give them study grants. Thus the researchers "own" the data and the government can claim they have no right to access it. Congress tried to close that

loophole with the "Shelby Amendment"⁷⁵ (for Sen. Richard Shelby, R-AL) which required data used for federal rulemaking to be available, but the original DASH contracts pre-dated the Shelby Amendment so, instead, we approached NHLBI seeking release of the data under the Data Quality Act (DQA).

The DQA requires federal agencies to use only quality data and one criterion is that the data can be re-analyzed and confirmed. Many groups from drug legalization advocates to greenhouse gas/climate change skeptics supported this requirement that was signed into law by President Bill Clinton. President George W. Bush installed as his director of Information and Regulatory Affairs, Dr. John Graham, former head of the Harvard University Center for Risk Analysis, an enthusiast for the new law.

Joined by the U.S. Chamber of Commerce, the Salt Institute petitioned for NHLBI to stop claiming that the data confirmed broad benefits for salt reduction as a finding of the DASH-Sodium study.⁷⁶ NHLBI first responded that the DQA petition was more properly an FOIA request – and denied it. We appealed.⁷⁷ They denied. The denials averred that the data had been or would shortly be released; a lie. We took the matter to court, the first solid appeal of a DQA case since the law had been enacted.⁷⁸ The facts were airtight, we felt. We lost. The trial court ruled we lacked standing to sue since the law didn't specify judicial appeals, adding gratuitously, that the government's depiction of the science was

persuasive as well. We appealed. And we lost when the appeals court ruled agencies were their own final judge of whether they'd satisfied their own rules under the DQA; the 3-judge panel expressed no views on the science itself. The DQA could not unlock the data.⁷⁹

At least the DASH-Sodium data exist and can be quarreled about. On some other points, the data simply do not exist. Government did not want to fund the studies to get them and others lacked the resources. This goes back more to the financial support theme, but can be considered another nuanced means to deny release of data on such crucial questions as health outcomes and the mutability of sodium appetite.

NHLBI's refusal to fund research to inform the debate and withholding relevant data have been an unfortunate blight on the quality of this issue debate.

The mantle of "evidence-based" recommendations

One would be hard put to find anyone who does not accept the proposition that public policy should reflect the best available evidence. With regard to public health nutrition, the case is even more compelling. As the saying goes: everyone is entitled to their own opinion, but no one is entitled to their own facts. Facts are facts. If the answer to a question is unknown, that is, itself, a fact.

75 A good summary has been prepared by the American Association for the Advancement of Science (<http://www.aaas.org/spp/cstc/briefs/accessto data/index.shtml>, accessed April 22, 2009).

76 May 14, 2003 (<http://www.saltinstitute.org/content/download/808/4482>)

77 September 22, 2003 (<http://www.saltinstitute.org/content/download/802/4458>)

78 Salt Institute news release, March 30, 2004 (<http://www.saltinstitute.org/content/download/789/4406>)

79 The issue may still be alive. A 2009 case has been heard in a different circuit court of appeals on a different issue, medical marijuana, so "the jury's still out." Since the DASH-Sodium data were used for the 2005 Dietary Guidelines and will be used in considering the 2010 Guidelines, this avenue cannot be resurrected until the 2015 Guidelines. The DQA prohibits the government from using data not available for independent confirmation. It is almost as if the law was not on the books. We should not be surprised, it has been 21 years since the Intersalt data were first reported and those data have yet to have independent review. So far, all the calls for quality science and transparency have been total window dressing, not real change.

Salt reduction activists have systematically adopted rhetoric embracing quality science. In practice, they rely for policy support not on the data but on expert-based recommendations.

The public is bombarded every week with medical studies produced by recognized experts, published in peer-reviewed journals, often well-regarded peer-reviewed journals, which offer directly conflicting findings and conclusions. Every policy-maker claims the mantle of employing an "evidence-based" process that results in "evidence-based" recommendations. This is a problem for anyone trying to make sense of the issue.

This is not a new problem. A quarter-century ago, Oxford scientist Dr. Archie Cochrane led an international effort to address the need to define quality evidence. He founded the now-global Cochrane Collaboration⁸⁰ which defined the process of "evidence-based medicine."⁸¹ "Process" is the key word here. The scientists understood clearly that the scientific process would yield results that were different than earlier studies – that is just how it works: further study can confirm an hypothesis...or not. The rigor of the process, then, determines the confidence we should place in the results. While researcher bias can be a concern, be it a strongly-held policy proclivity or a conflict-of-interest such as the potential influence of the corporate or government agency funding source, the "publish or perish" academic imperative, the career enhancement or ego needs of the researcher, all these yield in importance to misunderstandings rooted in assigning equal confidence in the products of different quality studies. A blinded, placebo-controlled randomized trial is the best level of evidence; the advice of experts is the lowest level.

The moral basis of American government is that we are a nation of laws, not of men. Likewise, scientific truth is the product of a legalistic "evidence-based" process, not the opinion of men. As such, evidence-based conclusions are rooted in a process that objectively pre-defines the rules by which

evidence will be considered and how it will be analyzed – all set out before the evidence is actually collected (and preliminary conclusions introduced that could bias the remainder of the process).

While the public is often told that an evidence-based process underlies a recommendation (e.g. the Dietary Guidelines), in fact, such "evidence-based reviews" often employ much lower standards (e.g., again, the Dietary Guidelines). Policy should reflect data, not opinion. It is the height of hypocrisy to insist that the opinion of an expert panel is an "evidence-based" process. Expert opinion is the lowest standard of evidence, far inferior to controlled interventions.

At least since 1990, the Salt Institute has consistently supported improving the process of developing population advice on salt and health. We have testified to every Dietary Guidelines Advisory Committee, warning that their expert panel approach would not (indeed, could not) produce evidence-based results. We've offered the same advice to other U.S. health agencies, Health Canada, the British health department, the European Union, the World Health Organization (WHO), and various advocacy groups. We've argued: Fix the process and the results will dispel the cacophony of the current policy discussion surrounding salt and health. We put the argument succinctly to WHO in 2002 commenting on the gap between a draft report and that report's professed process standards:

Look at the evidence. You must look at the evidence! Look at the standards accepted by the draft report: the need for high quality data, the need for "hard end points" and not just "intermediate variables" and the need for longer-term studies that capture the "lag time" of an individual's adjustment to a dietary intervention. The evidence establishes the importance of dietary changes to prevent chronic diseases. The data utterly fail to link reductions in dietary sodium intake levels to improved health outcomes in terms of reduced incidence of heart attacks, reduced incidence of stomach cancer or reduced incidence of bone fractures, the three "justifications" for the draft report's recommendation to lower dietary sodium intake by nearly half, from about 3,500 mg/day to 2,000 mg/day. The draft recommendations have no basis in

80 <http://www.cochrane.org/>

81 <http://www.cochrane.org/docs/ebm.htm>

science.⁸²

When the 2005 Dietary Guidelines Advisory Committee was named, we recommended at its first meeting it receive an invited lecture by the Cochrane Collaboration. Our advice went unheeded. With the same result, we renewed that suggestion for the 2010 Advisory Committee.⁸³

Myth-informing the public

Public relations misdirection

Like the magician's sleight-of-hand, misdirection in framing the salt and health debate has distracted serious attention from the "right question" of the target benefit and intervention efficacy of reducing dietary salt intakes. Over many years, NHLBI coupled its heavy investment in medical research with a massive public relations effort to change Americans' age-old love affair with salt, a dietary mainstay. Effectively so. Before the federal government painted a bulls-eye on salt, opinion pollsters probably would have found that 90% of Americans loved table salt and considered it an unmitigated blessing in their lives. Today that percentage is reversed and nine in ten "know" dietary salt is "bad for them." The PR resource disparity in the salt and health debate is overwhelming – but not enough to overwhelm the steady production of new science. Let's consider the "right answers" to dispel the various "myth-information" being pumped into the media.

The true issue is health outcomes, not blood pressure. NHLBI would like the world to think salt-sensitive blood pressure response is the overriding public health concern about population salt intake levels.

Fifteen years ago, salt reduction advocates might be forgiven for insisting that health outcomes effects of salt reduction were a nice

theoretical objective, such tests were impractical and the only option was to model outcomes based on blood pressure. "Everyone" knew that blood pressure was a risk with quantifiable health costs. So, they argued, simply figure out the magnitude of blood pressure reduction that could be achieved by reducing salt (itself often modeled) and then extrapolate. Presto: instant mega-scary numbers. But that was 15 years ago.

Dr. Michael Alderman of New York City is the editor-in-chief of the American Journal of Hypertension. Earlier he served as president of the American Society of Hypertension, then president of the International Society of Hypertension. In 1995, the American Heart Association journal Hypertension published Dr. Alderman's well-publicized observational study of his patients' health outcomes based on their baseline sodium intakes.⁸⁴ Though criticized for the crude methodology, the findings were paradigm-shattering: those on low-salt diets had 430% greater incidence of heart attacks. This was exactly the opposite result forecast by the government experts and their salt researcher acolytes. It was the first of at least a couple dozen health outcomes studies (more on the others later). It has become increasingly obvious that lowering salt intakes triggers other changes than blood pressure. Studies have confirmed that low-salt diets increase insulin resistance, elevate plasma renin activity and stimulate the production of aldosterone – all potent risk factors (like blood pressure, but operating in the opposite direction).⁸⁵

What would an advocate of reducing dietary salt do, confronted with mounting evidence that the intervention either did not work or

82 Richard L. Hanneman letter to Chizura Nishida, April 13, 2002 (<http://www.saltinstitute.org/content/download/831/457>).

83 Richard L. Hanneman letter to Carole Davis, May 21, 2008 (<http://www.saltinstitute.org/content/download/718/4122>).

84 Michael H. Alderman, et al.. "Low urinary sodium associated with greater risk of myocardial infarction among treated hypertensive men. Hypertension 1995; 25:1144-1152 (<http://hyper.ahajournals.org/cgi/content/abstract/25/6/1144>).

85 Salt Institute. "Will Reducing Dietary Salt Lower the Risk of Cardiovascular Disease?" Salt and Health newsletter, Winter 2006 (<http://www.saltinstitute.org/content/download/255/1471>).

actually, perversely raised the very risks the low salt advocate was espousing? What, indeed? NHLBI, CSPI, the AMA and others answered: ignore those data, consider only blood pressure. That may explain the government's refusal to fund the needed health outcomes study. Of course, we have advocated that study. So too has the Cochrane Collaboration, the U.S. Preventive Services Task Force and the 2005 the Dietary Guidelines Advisory Committee. Perhaps the Cochrane Collaboration put it best:

...raised blood pressure is only one risk factor for cardiovascular disease and overriding clinical benefits (or harms) of a low sodium diet are unclear. Revisiting all the participants of the large trials in people without hypertension some years later to assess long term effects of low sodium dietary advice on mortality and cardiovascular morbidity would be a cost effective and relatively rapid way to assess the clinical effectiveness of advice to reduce sodium intake. There is strong justification for a large-scale, long term randomized controlled trial to explore the cost effectiveness of such advice if it is to remain a part of the strategy for prevention and treatment of hypertension.⁸⁶

The Salt Institute endorsed health outcomes from the first publication of the Alderman article in 1995 which incontrovertibly established the legitimacy of health outcomes as the defining public health objective. In fact, it is immoral and unethical to continue a focus solely on blood pressure now knowing that science has confirmed that lowering dietary salt intake produces unintended, compensating and adverse health consequences.

We at the Salt Institute were slow to abandon our efforts to correct misstatements about the salt: blood pressure relationship. We mistakenly spent several years commenting on the continued flow of blood pressure studies being generated, funded by NHLBI. Now, it is perfectly clear: the blood pressure story will always be contentious; it is, after all,

based on a well-established (if poorly understood) link of salt and blood pressure. Beginning in mid-2001, the Salt Institute has done better in resisting the temptation to comment on blood pressure studies beyond pointing out that they really address the wrong question.

In July 2004, we urged the Dietary Guidelines Advisory Committee to push for a health outcomes study first. We recommended:

"1. An ALLHAT-type clinical trial of health outcomes of salt restriction. This will be costly, but affordable. It would be a propitious investment given the enormous costs imposed by heart attacks and strokes and the lack of even a single trial of the health outcomes of the sodium reduction recommendation in the Guidelines. 2. A clinical trial, over a six-month period, comparing the blood pressure impacts of four groups: a control group, a diuretics-only group, a DASH group and a DASH-low sodium group. This would provide useful insights into the relative effectiveness of several optional strategies and allow for prioritization of scarce implementation resources on the most effective approaches. 3. A study to defend the cost-benefits of non-pharmacologic interventions with regard to cardiovascular disease. With the high and rising costs of drugs, Americans might be more easily persuaded to pursue food-based lifestyle changes if they understood the high cost of realizing equivalent benefits through pharmacologic therapies. Such a study could compare the cost-benefits of pharmacologic versus non-pharmacologic strategies. 4. An analysis of how consumers actually process low-salt dietary advice and how they incorporate that advice into their food purchasing and preparation decisions. The Guidelines have encouraged the notion of moderation or reduction since 1980, but sodium intakes are unchanged (unchanged, as well, over the past century). Clearly, the advice as it is being packaged is not effective, so the medium and the message both should bear scrutiny. 5. A study of salt as a feed-limiter in humans. Feedlot nutritionists use the predictable and unchanging intake levels of dietary salt by livestock and poultry to meter trace mineral nutrients and prescribed medications – and put animals on "low salt" diets to induce increased caloric consumption. If humans

86 Lee Hooper, et al. "Systematic review of long term effects of advice to reduce dietary salt in adults." *British Medical Journal*, 2002; 325:628-636 (<http://www.bmj.com/cgi/content/abstract/325/7365/628>).

are like these species of livestock and poultry, their bodies may be using salt as a feed limiter with the perverse consequence that attempts to limit dietary sodium in free-living populations may be inducing them to consume more foods (and more calories) until their bodies say "enough."⁸⁷

The final report did recommend a health outcomes study, but NHLBI has never funded it.

More recently, a team of New York researchers produced three analyses of the federal nutrition and health database (NHANES, the National Health and Nutrition Examination Survey). The latest showed that in average, healthy Americans, those consuming the recommended 2,300 mg/day sodium had 37% more cardiovascular deaths – greater risk of dying by one-third than those who tuned out to this "healthy" advice.⁸⁸

Although sometimes it seemed as if no one was listening, in fact, this message has been gaining traction. Opponents seized on their first bit of "health outcomes" evidence they felt supported their anti-salt advocacy and crowed about the success of Finland over the past 30 year in reducing salt intake and achieving significant reductions in both rates of heart disease and extending life expectancy. We congratulated them for embracing a health outcomes mentality and then pointed out that if Finland had, indeed, cut salt as they claim, their improved rates of heart disease and extended lifespan should be compared to other similar countries which had not reduced dietary salt (i.e. all the rest). It turned out that Finland's rate of heart disease improvement was half that achieved by Canada and less than any nearby European

country or the U.S. Over the 30 year period, Finns were living 5.5 years longer; Americans, 8.5 years. Perhaps, we suggested, salt reduction may be responsible, but, if so, it was responsible for retarding the health improvements achieved by its non-salt-reducing peers.⁸⁹

One study, however, has documented improved health for those on low-salt diets.⁹⁰ So, even without digging into its methods and analysis, it would be fair to say that the evidence is inconclusive. It is totally consistent, however on one point: overall there is no pattern of support for the cherished assumptions that lowering population salt intakes will improve public health. And, in that conclusion, it destroys the credibility of salt reduction activists who stubbornly cling to the wrong question by insisting on a focus only on blood pressure in preference to hard end-point health outcomes.

The true issue is diet quality, not food. A generation ago, every dietitian would quickly agree that "there are no 'good foods' or 'bad foods,' only 'good diets' and 'bad diets.'" That consensus is surely shattered. CSPI's fundraising letters promise secrets of "10 foods you should never eat."⁹¹ Newspapers are filled with good food/bad food stories and the Dietary Guidelines has turned its back on food, embracing advice to meter nutrient intakes instead. The truth is: people do not eat nutrients, they eat foods. We "buy" the entire nutrient package when we eat a banana or drink a glass of milk. But more than that, when we eat a salt-laden pickle, it likely will have no impact at all on our weekly sodium

87 Richard L. Hanneman to Kathryn McMurry, July 16, 2004 (<http://www.saltinstitute.org/content/download/780/4370>).

88 Hillel W. Cohen, et al, Sodium Intake and Mortality Follow-Up in the Third National Health and Nutrition Examination Survey (NHANES III), *Journal of General Internal Medicine*, May 9, 2008, 23 (9) 1297-1302 (<http://www.springerlink.com/content/51x081vzv76v9204/?p=f60916e8e39049deaeae26fb4ad5fc96&pi=0>).

89 Morton Satin, "Health Outcomes Lessons from Finland's Salt Reduction," *Salt and Health newsletter*, Summer 2007 (<http://www.saltinstitute.org/content/download/259/1487>).

90 Nancy R. Cook, et al. Long term effects of dietary sodium reduction on cardiovascular disease outcomes: observational follow-up of the trials of hypertension prevention (TOHP). *British Medical Journal*, April 28, 2007;334:885 (<http://www.bmj.com/cgi/content/abstract/334/7599/885>).

91 See for example CSPI's online promotion at http://www.cspinet.org/nah/10foods_bad.html

intake. Clear evidence shows the important link of overall dietary quality to chronic disease incidence.⁹² As we make food choices, we construct our diets, but rating foods on their nutrient profile rather than rating an overall dietary pattern is another scientific dead-end street.

The true issue is health outcomes, not implementation. This is a very different issue from the blood pressure versus health outcomes question. Recognizing that the public receives mixed messages about whether reducing dietary salt will be healthy for them, and, perhaps, recognizing that respected scientists and journalists regularly fuel the scientific controversy with new, skeptical reports, proponents of salt reduction have tried simply to “declare victory and move on” to implementing the “consensus” they claim support universal salt reduction. In this, they try to marginalize dissent, implying that those “still” debating whether reducing salt is healthy or not are clearly uninformed, special pleaders or in some other way irrelevant. The real action, they aver, is tackling the very significant challenges of inducing reduction of actual sodium intakes.

NHLBI tried this ploy early-on and Environment Canada launched such an effort in 2007. NHLBI called industry together in 1999 to plan “how” to achieve reductions and was greeted by scientists in the audience insisting that the agency prove the wisdom of the policy objective.⁹³ Despite policy

pronouncements from Canadian scientists (including one of its own departments) that questioned a population strategy, Environment Canada created a stakeholders group to provide guidance on “how” to reduce population salt intakes. It ignored protestations that its goal was not science-based.⁹⁴ The same arrogance plays out in the U.S. salt and health debate. NHLBI refuses to fund the fundamental health outcomes study. The Dietary Guidelines endorsing the (still-unfunded) study while at the same time adopting more strident language as if the study had been done and confirmed the salt hypothesis.

The truth is that a 60% cut in salt intake is not “modest”. Far too many news reports mindlessly echo salt reduction activists’ portrayal of a 60% reduction in current intake levels as “modest.” A 60% reduction in anything is anything but modest. The assertion misleadingly suggests that achieving a significant reduction is relatively easy. The Trials of Hypertension Prevention, phase 2,⁹⁵ maintained a large number of highly-motivated volunteers, compensated for their participation, on a 25% salt reduced diet using regular coaching and encouragement from the researchers – but only for 36 months, far shorter than the average lifespan of Americans being asked to follow a low-salt diet. A 60% reduction is hardly modest.

The true issue is salt appetite, not taste or consumer behavioral motivation. Salt reduction activists blithely assume that an individual’s salt intake is a product of their self-discipline in shunning salt. They dub an intake over 500 mg/day sodium as “excessive,” despite the fact that the kidney in a healthy person has vast capacity to process this “excess” safely. At “recommended” levels – well above that “needed” by the body

embarrassing to NHLBI

(http://www.nhlbi.nih.gov/health/prof/heart/hbp/salt_sum.htm).

94 Morton Satin letter to Laurie Throness, Health Canada, November 21, 2007.

95 NHLBI, Trials of Hypertension Prevention, phases I and II, (<http://www.nhlbi.nih.gov/resources/deca/descriptions/tohp.htm>)

92 Ashima K. Kant, et al. A Prospective Study of Diet Quality and Mortality in Women, *Journal of the American Medical Association (JAMA)*, April 26, 2000; 283:2109-2115

(<http://jama.ama-assn.org/cgi/content/abstract/283/16/2109>) and Andrew Mente, et al. A Systematic Review of the Evidence Supporting a Causal Link Between Dietary Factors and Coronary Heart Disease, *Archives of Internal Medicine*. April 13, 2009; 169(7):659-669 (<http://archinte.ama-assn.org/cgi/content/abstract/169/7/659>).

93 The meeting is reported by NHLBI through its co-chairs Aram Chobanian and Martha Hill. Their report omitted the commentaries from the floor that would be

– but far lower than today's intakes – the body senses insufficient salt and backup systems kick in, generating hormones that raise the risk of heart attacks. Individual needs vary and they vary based on multiple factors over time so while individual set-points may vary, so too do any individual's requirements depending on temperature, level of activity, etc. The issue isn't that consumers are ill-informed, insufficiently motivated or victims of the food industry's alleged use of unnecessary "excess" salt; the truth is that the brain senses how much salt we need and centrally regulates sodium appetite. Playing on consumer guilt or stoking anger at food manufacturers for victimizing their customers has no evidentiary support.

So what lessons should be learned from evidence-based science?

Lessons from current science

- Salt affects blood pressure in a heterogeneous manner and its blood pressure effect is heavily impacted by the impact of other dietary electrolytes
- Salt intake levels also affect insulin resistance, plasma renin activity, aldosterone production and sympathetic nervous system activity
- The net effect of salt reduction has been investigated in less than 20 studies and only one randomized controlled trial, and that in only an abnormally high risk population
- Population salt intakes range narrowly and consistently over time, but salt requirements vary between persons and vary in individuals over time with activity, illness, etc.
- It's likely salt appetite is a central nervous system (CNS)-determined parameter
- Food technologists have made dramatic reductions in the per-serving salt content of many foods, but there are limits to salt reduction in terms of food safety and consumer acceptance
- No studies have examined either the sodium intake changes nor the health consequences of replacing "normal" sodium foods with "low-sodium" substitutes

- No study has examined the health consequences of large-scale substitution of salt with salt substitutes
- There is no population health benefit attributable to low-salt diets

Salt affects blood pressure in a heterogeneous manner and its blood pressure effect is heavily impacted by the impact of other dietary electrolytes

Although high quality studies at the University of Indiana long ago established that different individuals' blood pressure responds differently to reduction of dietary salt,⁹⁶ the two DASH studies show that salt-sensitivity in blood pressure is virtually eliminated on diets rich in fruits, vegetables and dairy products.

Salt intake levels also affect insulin resistance, plasma renin activity, aldosterone production and sympathetic nervous system activity

The founder of the American Society of Hypertension, John Laragh, won a coveted Time magazine cover photo/story back in the 1970s for his pioneering work describing the important role that the renin-angiotensin system plays in cardiovascular risk.⁹⁷ His frequent co-investigator, Michael Alderman, has extended that work, further documenting the adverse CV events that can be expected when individuals' plasma renin activity rises – as it does when salt intakes are reduced.⁹⁸ Although the hormone aldosterone was

96 For example, Myron H. Weinberger, "Salt Sensitivity of Blood Pressure in Humans," *Hypertension*, 1996; 27:481-490 (<http://hyper.ahajournals.org/cgi/content/abstract/27/3/481>).

97 "Hypertension: Conquering the Quiet Killer," *Time*, January 13, 1975 (<http://www.time.com/time/covers/0,16641,19750113,00.html>).

98 For example, see Michael H. Alderman, et al, "Plasma Renin Activity: A Risk Factor for Myocardial Infarction in Hypertensive Patients." *American Journal of Hypertension*. 1997; 10, 01–08 (<http://www.nature.com/ajh/journal/v10/n1/abs/ajh19971a.html>).

discovered about the same time, more than 50 years ago, its immense impact on the cardiovascular system has only recently been appreciated.⁹⁹ Many experts consider aldosterone to be the most important cardiovascular hormone in the human body. It too, is secreted when the body senses inadequate salt intakes. More than 50 studies have documented that low salt diets produce the "unintended consequence" of increasing insulin resistance.¹⁰⁰ Low-salt diets also increase sympathetic nerve activity and decrease tissue perfusions, two other factors worsened by insulin resistance.

The net effect of salt reduction has been investigated in less than 20 studies and only one randomized controlled trial, and that in only an abnormally high risk population

Dr. Alderman's 1995 study of the health outcomes of his hypertensive patients unleashed a storm of controversy, contradicting as it did the worldview being disseminated by NHLBI and its acolytes. There are still relatively few health outcomes studies examining salt intakes with regard to CV events or mortality.¹⁰¹ Most of them

99 Morton Satin, "Aldosterone: Unlocking our Understanding of Cardiovascular Risk," Salt and Health newsletter, Summer 2008

(<http://www.saltinstitute.org/content/download/273/1548>).

100 Morton Satin, "Low-salt Diets and Insulin Resistance," Salt and Health newsletter, Spring 2008

(<http://www.saltinstitute.org/content/download/271/1539>).

101 In addition to the studies already cited by Alderman (1995), Cohen, two by Paterna, Cook and Cohen (2008), there have been a number of others, some published, others presented at professional meetings. These include the following"

- A. Kagan, et. al. "Dietary and other risk factors for stroke in Hawaiian Japanese men." *Stroke*, 1985; 16:390-396.
- Jeffrey R. Cutler, Presented May 30, 1997, at American Society of Hypertension annual meeting,

San Francisco, CA.
(unpublished).

- Hugh Tunsall-Pedoe.
"Comparison by prediction of 27 factors of coronary heart disease and health in men and women of the Scottish heart health study cohort study. *British Medical Journal*, 1997; 315:722-729.
See Table 6, age-adjusted hazard ratios.
- Michael Alderman, et al. "Dietary sodium intake and mortality: the National Health and Nutrition Examination Survey (NHANES I)." *Lancet* 1998; 351:781-785.
- V-P Valkonen. "Sodium and potassium excretion and the risk of acute myocardial infarction" Presented October 15, 1998 to the American Heart Association Scientific Sessions, Dallas, TX (unpublished).
- Jerome D. Cohen. presentation to NHLBI Workshop on Sodium and Blood Pressure, January 28, 1999, Bethesda, MD (unpublished)
- J. He, et al. "Dietary sodium intake and subsequent risk of cardiovascular disease in overweight adults." *Journal of the American Medical Association*, 1999; 282:2027-2034.
- J. Tuomilehto, et al. "Urinary sodium excretion and cardiovascular mortality in Finland: a prospective study." *Lancet*. 2001; 357:848-51.
- D.E. Grobbee. et al. "Sodium and potassium intake and risk of cardiovascular events and all-cause mortality: the Rotterdam Study" presented to the 13th European Meeting on Hypertension in Milan, Italy, June 13-17, 2003 (published abstract)
- C. Nagata, et al. "Sodium intake and risk of death from stroke in Japanese men and women." *Stroke*. 2004; 35:1543-1547.
- Hillel Cohen, et al. "Sodium intake and mortality in the NHANES II follow-up study." *American Journal of Medicine*. 2006; 119,275.e7-275.e14

have found either no benefit at all in reducing dietary salt or even increased risks. Until the past year, all the health outcomes studies were observational, that is, they were not controlled for confounding factors nor conducted prospectively. These are an admittedly lower level of evidence (higher than expert opinion, however).

On the basis of the observational studies, there would not even be enough evidence to warrant a controlled trial to determine if reducing dietary salt is a good idea – except that the recommendation is already enshrined as public policy.

The first randomized controlled trial of the health outcomes of low salt diets was published in December 2008 by an Italian research group;¹⁰² it published a second paper two months later.¹⁰³ For more than a

half century, the first intervention ordered by doctors treating congestive heart failure has been to order salt reduction. As in the salt hypothesis, the logic was compelling, if untested. The researchers did test it, however, and discovered to the amazement of virtually everyone that in this high-risk population “known” to benefit from low-salt diets, those who actually received the lower salt diets had greater morality and more frequent re-hospitalizations. This is further, compelling evidence of the need for a controlled trial in the healthy population. To do otherwise, and proceed to try to force the population onto lower salt intakes, is to make the entire population a virtual “guinea pig” for the untested salt hypothesis.

Population salt intakes range narrowly and consistently over time, but salt requirements vary between persons and vary in individuals over time with activity, illness, etc.

Although controlled trials have successfully lowered sodium intakes in experimental settings, such “success” of low-salt diets has not been achieved in the free-living population unless the population was consuming abnormally high salt diets already as was the case in Finland, Japan and China. Prominent Swedish researcher Björn Folkow calculated the “hygienic safety range” for sodium intake to be 100 – 200 mmol or perhaps 250 at the high end.¹⁰⁴ This is 2,300 mg/day Na to 4,600 mg/day or perhaps as much as 5,750 mg/day. That is, the government’s recommendation would place a significant portion of the population below the minimum intake level for safety. Another study confirmed that when subjects in a controlled trial were able to select their own salt intakes, they fell in the 130 – 180 mmol Na range (roughly 3,000 – 4,000 mg/day Na).¹⁰⁵ It seems clear that humans

- T. Shimazu, et al. "Dietary patterns and cardiovascular disease mortality in Japan: a prospective cohort study." *International Journal of Epidemiology*. 2007; 36:1: 1-10.
- J.M. Geleijnse, et al. "Sodium and potassium intake and risk of cardiovascular events and all-cause mortality: the Rotterdam Study." *European Journal of Epidemiology*. 2007; 10.1007/s10654-007-9186-2.
- S.C. Larsson, et al. "Magnesium, calcium, potassium and sodium intakes and risk of stroke in male smokers." *Archives of Internal Medicine*, 2008; 168 (No 5), 459-465 (March 10, 2008).

102 Salvatore Paterna, et al
“Normal-sodium diet compared with low-sodium diet in compensated congestive heart failure: is sodium an old enemy or a new friend?” *Clinical Science*. 2008; 114:221-230
(<http://www.clinsci.org/cs/114/0221/1140221.pdf>).

103 Salvatore Paterna, et al. “Medium Term Effects of Different Dosage of Diuretic, Sodium, and Fluid Administration on Neurohormonal and Clinical Outcome in Patients With Recently Compensated Heart Failure. January 1, 2009; 103(1):93-102

([http://www.ajconline.org/article/S0002-9149\(08\)01453-7/abstract](http://www.ajconline.org/article/S0002-9149(08)01453-7/abstract)).

104 Björn Folkow. “Salt and Hypertension.” *News in Physiological Sciences*. 1990;5:220-224.

105 S.G. Chrysant et al. “Effects of isradipine or enalapril on blood pressure in salt-sensitive hypertensives during low and high dietary salt intake. MIST II Trial Investigators. *American Journal of Hypertension*, November 2000;

are like all known species of livestock and poultry in having predictable salt intakes

13(11):1180-8

(<http://www.nature.com/ajh/journal/v13/n11/abs/ajh2000192a.html>). Evidence collected in the Sandoz MIST calcium channel-blocker drug trial is most instructive. The methodology on this double-blind, randomized controlled trial called for all subjects to be trained to consume low-sodium diets, free choice; those who were unable to achieve a 70 mmol Na diet were excluded from the trial. In the intervention, all subjects were counseled to continue their low-sodium diet, but add a pill. In the first stage of the intervention, half received a placebo, half, 100 mmol of sodium. Excretions were monitored. Quickly, those receiving the sodium increased their urinary sodium excretion to about 170 mmol as would have been predicted. But, surprise, those who, though blinded, received the placebo, increased their urinary sodium output to about 110 mmol. After the first phase, the groups continued to take a pill a day, but those who had received the placebo now received the sodium and vice versa. What happened? Those who had received the placebo, but who had "cheated" by adding 40 mmol of sodium were given 100 mmol more. Did they jump to 210 mmol? No, their sodium excretion increased to about 170 mmol; in other words, they stopped "cheating" even though there were no clues about what they had been consuming. And the other group? Those who had been getting the 100 mmol sodium pill would be expected to revert back to the baseline 70 mmol sodium excretion level reflecting that their pill had changed to sugar. But, no. Even though there was no "signal" given, this group started "cheating" when given the placebo; their excretion was, again, about 110 mmol. This is more than a nice story. In the MIST trial, the evidence suggests that the body has a natural appetite for sodium in the range of about 110-170 mmol. After all, most societies in the world with free access to salt consume salt in this range; the U.S. is right in the middle of this range.

when NaCl is available "free choice."¹⁰⁶

It's likely salt appetite is CNS -determined

The article "Central Regulation of Sodium Appetite" in the February 2008 edition of *Experimental Physiology* gives a plausible explanation of the mechanisms involved.¹⁰⁷

Food technologists have made dramatic reductions in the per-serving salt content of many foods, but there are limits to salt reduction in terms of food safety and consumer acceptance

Over the past two years, food manufacturers, particularly in the U.S. and the U.K. have reported overall significant reductions in the salt content of their foods, but also a stiffening resistance to further reductions which they say threaten to compromise consumer acceptance and approach the minimums required to ensure food safety.¹⁰⁸

No studies have examined replacing "normal" sodium foods with "low-sodium" substitutes; neither the sodium intake changes nor the health consequences

Current salt reduction initiatives are founded on the assumption that salt intake is achievable by replacing replace foods with "normal" sodium content with "low sodium" foods. This might be achieved voluntarily, the activists argue, by consumer education on improved nutrition labeling or, failing that, by inducing food manufacturers to reduce the salt content of their products. Re-engineering the food supply might be voluntary or imposed by regulatory fiat. Yet, if "salt appetite" is scientifically verifiable, this entire house of cards collapses. Indeed,

106 Larry L. Berger, *Salt and Trace Minerals for Livestock, Poultry and other Animals*, Salt Institute, 2006 (<http://www.saltinstitute.org/content/download/4377/23799>).

107 Geerling, op cit footnote 33.

108 Grocery Manufacturers Association. *Sodium and Salt: A Guide for Consumers, Policymakers and the Media*, January 12, 2009 (http://www.gmabrands.com/publications/SP_SodiumFINAL.pdf).

in that situation, the scorn of the news media would soon be redirected in sympathy to the victims of the food industry's unconscionable foisting of "excess" foods on their customers knowing full-well that low-salt servings would mean additional food consumption. Food manufacturers may be setting themselves up by actually brag that they have been engaged in small but cumulative "stealth" reductions of the salt content of their products and developing thousands of low-salt products. Perversely, citizens trying hardest to follow the Dietary Guidelines are most at risk.

No study has examined the health consequences of large-scale substitution of salt with salt substitutes

Earlier this year, the Salt Institute's Mort Satin testified to the Institute of Medicine warning them of the potential harm of promoting large scale use of salt replacements which he termed "an arsenal of synthetic chemical products that have never been tested for their interactions and toxicities at the projected levels." He equated such a strategy as "little different than replacing hard animal fats with trans fats or cane sugar with the several industrial chemicals we call sugar replacers today" and predicted that "sooner or later, a fuller understanding of their toxicities will be revealed, but no one will be around to take responsibility for the ill-conceived strategy that prompted them."¹⁰⁹

There is no population health benefit attributable to low-salt diets

This is the bottom line. Salt reduction would be difficult if not impossible, but fortunately it is unnecessary in populations, except possibly those with intakes over 200 – 250 mmol Na. The potential danger may lie less in the adverse consequences of low-sodium diets themselves, since consumers are most likely to satisfy their salt appetite to consume the amount signaled by their brain, not their taste buds. The greater

danger is that in the attempt to follow dietary advice for "health," they may trigger the unintended consequence of aggravating already excessive caloric intakes.

The path forward, recommendations 2010-2015

There are four steps urgently needed to get us back on the road to improving our diets for better health and reduce the risks of chronic disease. Unlike the vagaries attendant to the strategy of universal salt reduction, these have far greater predictability and the likelihood of tremendous benefit-cost advantages. The four steps include the following:

- Adopt evidence-based approach for dietary recommendations
- Split research and dietary education/advocacy
- Study salt appetite
- Study health outcomes of low-salt diets

Adopt an evidence-based approach for dietary recommendations

The U.S. should embrace the rigorous methodology developed and promoted by the Cochrane Collaboration as recommended by the U.S. Preventive Services Task Force, part of the Department of Health and Human Services. Other countries should adopt the Cochrane discipline.

Split research and dietary education/advocacy

The U.S. should restore the credibility of its science base by tasking NHLBI with the singular role of investigating the science. A separate agency should assume responsibility for public education/advocacy to prevent chronic disease and promote improved health. In other countries, where these functions are combined, they should be split between independent units.

Study salt appetite

Before government bureaucrats launch into behavior modification or force food manufacturers to re-engineer their products, we should invest in quality science on the question of whether salt appetite is CNS-determined and, therefore, immutable or

109 "Institute of Medicine cautioned on dangers of population-wide salt reduction." Salt Institute news release, March 31, 2009 (<http://www.saltinstitute.org/content/download/8470/45614>).

whether conscious consumer food choices can significantly affect total sodium intake levels.

Study health outcomes of low-salt diets

Last and most important, inherent in step one, above, the federal government should fund – and seek support from health ministries in other countries – a Cochrane-quality prospective controlled trial of the question: will salt reduced diets improve health? We think we know the answer: no. But we really owe it to ourselves to do a solid investigation. If science cannot confirm a health benefit for such a drastic intervention, we ought to move on to other options.

Supported by the Salt Institute