FDA's Dietary Sodium Initiative in the War Against Hypertension, a New Weapon

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SYNOPSIS

The Food and Drug Administration is engaged in a broad-based program to make consumers more aware of the potential impact on health of sodium consumption well in excess of dietary needs; to encourage food manufacturers to lower the amounts of sodium they add to their products, where this is safe and feasible; and to provide information to consumers about the sodium content of the foods they buy and use. This program is expected to be a significant preventive public health measure against hypertension.

H YPERTENSION is one of America's most serious and pervasive public health problems. It is the leading cause of stroke in the United States and a major contributor to deaths from heart attack, heart failure, and kidney disease. The Hypertension Task Force of the National Heart, Lung, and Blood Institute has estimated that the number of hypertensive persons in the United States ranges from 23 million to as many as 60 million, depending on the criteria used to define hypertension (1,2).

There is no way to determine with certainty who will develop hypertension. Yet, if incidence rates remain at their current levels, as much as 70 percent of the present population will develop definite or borderline hypertension by age 65 (3).

Because hypertension for the most part is asymptomatic, it also may progress without detection. Despite the efforts of the National High Blood Pressure Education Program, as many as one-third of the nation's hypertensives remain undetected. Obviously, one goal of a comprehensive hypertension program would be to identify those individuals.

The Department of Health and Human Services is concerned about all aspects of hypertension and is funding basic and applied research in several scientific disciplines. The results of such research efforts will continue to add to basic knowledge of the mechanisms underlying hypertension.

It is, however, prudent public health policy to implement prevention programs when knowledge is sufficient to suggest that they will have a significant positive effect. Success has certainly been achieved in recent years through weight control programs and the judicious use of drug therapy in the treatment of hypertension. The dietary sodium content and labeling initiatives of the Food and Drug Administration (FDA) and the Department of Health and Human Services, which were begun about a year ago, hold potential for important gains in achieving better control of hypertension in the population.

An Emerging Consensus

Although more research is needed before biomedical scientists fully understand the multifactorial aspects of hypertension, a consensus is emerging in the biomedical community that moderation in dietary sodium intake is a prudent public health objective. This consensus applies not only with respect to the care of persons on sodium-restricted diets because of known hypertensive disease but also with respect to the general population (which includes substantial numbers of undiagnosed hypertensives) because of the hypothesis that there is a relationship between high sodium intake and the pathogenesis of high blood pressure. Among key segments of the biomedical community expressing these views are the American Medical Association 'There is no way to determine with certainty who will develop hypertension. Yet, if incidence rates remain at their current levels, as much as 70 percent of the present population will develop definite or borderline hypertension by age 65.'

(4); the Task Force of the American Society for Clinical Nutrition on the Evidence Relating Six Dietary Factors to the Nation's Health (5); the Hypertension Task Force of the National Heart, Lung, and Blood Institute (1); the Food and Nutrition Board of the National Academy of Sciences -National Research Council (6); and the Select Committee on Generally-Recognized-as-Safe Substances of the Federation of American Societies for Experimental Biology (7). The Senate Select Committee on Nutrition and Human Needs (8) and the Department of Health and Human Services in conjunction with the Department of Agriculture (9) have also called attention to the relationship between dietary sodium and hypertension.

The same general conclusion emerged from the March 1982 Symposium on Current Perspectives in Hypertension (organized by experts from Columbia University, the University of Oregon Health Sciences Center, and the University of Iowa, and sponsored by the Campbell Soup Company) and the September 1982 Conference on Nutrition and Blood Pressure Control—Current Status of Dietary Factors and Hypertension (10), sponsored by the National Kidney Foundation, the Department of Health and Human Services, and the International Life Sciences Institute.

The report of the Hypertension Task Force states that, on the basis of current knowledge, "it would be prudent for normotensive and hypertensive individuals to avoid injudicious use of salt whenever possible" (11). Similarly, the Council on Scientific Affairs of the American Medical Association recommended moderation of salt intake for the entire population(4).

Several studies suggest that restricting dietary intake of sodium reduces blood pressure in many persons who have mild hypertension, and that it may do so for "sodium sensitive" persons with moderate to severe hypertension (12-14). There is evidence

that dietary sodium restriction is a useful adjunct to antihypertensive drug therapy (13). Studies also suggest that the onset of hypertension in susceptible individuals may be delayed by dietary sodium restriction, thereby reducing the risk of other associated diseases.

In view of these facts and my own clinical and scientific experience with hypertension, I am firmly convinced that salt consumption well in excess of need may contribute to the development or exacerbation of hypertension and that it would be prudent for the general population to moderate its sodium intake.

There is no way to determine which of us is susceptible to the development of hypertension; however, knowing that large numbers of the population will develop the condition and that moderation in sodium intake may reduce both the incidence and the severity of hypertension in some individuals, I concluded that a program to achieve moderation in dietary sodium intake has the potential of being a significant preventive public health measure against hypertension. This is especially so in light of the fact that the average dietary intake of sodium is well in excess of dietary needs and that there is no evidence to suggest that a moderate reduction in sodium intake for the general public would have any adverse health effect.

The FDA Initiative

The FDA's sodium initiative has five objectives that were first enumerated in testimony by the FDA Deputy Commissioner, on April 14, 1981, before the Subcommittee on Investigations and Oversight of the House Committee on Science and Technology. These objectives are:

• to encourage the food industry voluntarily to reduce the amount of sodium added to foods and to market a greater variety of foods that are lower in sodium;

• to increase the amount and effectiveness of sodium-content labeling of foods by issuing new rules governing such labeling and encouraging the food industry to provide more quantitative sodium declaration on food labels;

• to work with industry, other government agencies, and interested nongovernment organizations to help consumers make the most effective use of sodium labeling and to increase consumer awareness of the health impact of dietary intake of sodium well in excess of physiological need; • to monitor changes in sodium consumption and sodium content of foods, trends in sodium labeling of retail foods, and shifts in consumer perceptions and marketplace practices—all in order to assess progress toward achieving objectives; and

• to consider the need for legislation in the event this voluntary program does not succeed.

This program was discussed with food industry representatives on June 30, 1981, and was presented in detail in the Federal Register proposal of June 18, 1982 (47 FR 26580). Both the Department of Health and Human Services and the FDA have stressed that the goals of the sodium program are to provide more information to the public about the sodium content of foods they buy and to encourage industry to reduce the amount of sodium in processed foods, where this is safe and feasible.

Results have been encouraging. For example, several major food manufacturers have stated that they will supply sodium labeling for all of their products containing more than 35 mg of sodium per serving. In addition, many manufacturers have indicated that they have programs in progress to study the feasibility of reducing sodium in their products. FDA representatives have met with some 30 major groups from the food industry, including both large individual firms and trade associations representing them. Each of these groups has made a commitment either to moderate the sodium content of the foods they process or to provide much more sodium labeling. Collectively, these efforts already affect processed foods amounting to many billions of dollars in retail sales value. We estimate that the amount of sodium labeling in the marketplace will double or triple over the next year, applying to 40 percent or more of the processed food supply in terms of retail sales value. By mid-1982, 19 percent (by dollar volume) of the foods regulated by FDA carried quantitative sodium labeling, up from 14 percent in the preceding year.

We believe that another positive aspect of the program has been the perspective and balance that have been built into it. We are not advocating measures that have the potential for risk to the population. We simply seek to lower sodium consumption to a moderate level—one that still will provide more than two times the physiological need for sodium for virtually all environmental conditions. We recognize that hypertension is likely to have a multifactorial etiology and that other hypotheses, not associated with sodium intake, have been put forth that may be proven to be valid for some individuals. No 'We are not advocating measures that have the potential for risk to the population. We simply seek to lower sodium consumption to a moderate level—one that still will provide more than two times the physiological need for sodium for virtually all environmental conditions.'

aspect of our program is designed to conflict in any way with the investigation of such hypotheses, and we encourage continued research where such hypotheses are judged to have merit.

But the most significant part of this program, from a scientific perspective, is its capacity to measure any positive or negative benefits that accrue as the program is implemented. The FDA is currently involved in several monitoring programs designed to do just that. These programs include measurement of sodium consumption and the prevalence of hypertension in the population, estimation of the prevalence of quantitative sodium declarations on the labels of processed foods, and annual assessment of the effectiveness of public education campaigns and the impact of the sodium-labeling initiative on buying habits. A thorough discussion of this aspect of the overall program was presented in the September-October 1982 issue of Hypertension (10a).

These efforts, together with fundamental and applied research by the National Institutes of Health, will contribute measurably to our understanding of the basic mechanisms underlying development of hypertension and to our knowledge about the benefits of moderation of sodium intake as a preventive measure.

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Surveillance and Control of Infectious Diseases: Progress Toward the 1990 Objectives

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G REAT PROGRESS HAS BEEN MADE in the United States in this century in reducing mortality attributable to infectious diseases. Infectious diseases were the fourth leading cause of death in the United States in 1976 (fig. 1) after heart disease, malignant neoplasms, and cerebrovascular diseases, according to data extracted from information published by the National Center for Health Statistics (1). Data are not available for all infectious diseases, but in 1980, influenza and pneumonia ranked seventh in years of potential life lost by the total U.S. population ages 1 to 64 years (2), as the following tabulation shows. health-dietary guidelines for Americans. Consumer Information Center, Pueblo, Colo., 1980.

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SYNOPSIS

Great progress has been made in the United States in reducing infectious disease mortality. However, infectious diseases remain the greatest cause of morbidity in this country. Newer infectious diseases or agents have been recognized, but newer tools for surveillance and control have also been made available. Specific objectives for the reduction of infectious diseases by 1990 have been set by the Public Health Service. The opportunities appear to be good for achieving by 1990 objectives for nosocomial infections, Legionnaires' disease, tuberculosis, and surveillance and control of infectious diseases. Achievement of the 1990 objectives for hepatitis B, pneumococcal pneumonia, and bacterial meningitis, however, will require both scientific advances and additional resources.

Cause	Total years lost
1. Accidents and adverse effects	2,684,850
2. Malignant neoplasms	1,804,120
3. Diseases of the heart	1,636,510
4. Suicides, homicides	1,401,880
5. Chronic liver disease	301,070
6. Cerebrovascular diseases	280,430
7. Pneumonia and influenza	124,830
8. Diabetes mellitus	117,340
9. Chronic obstructive pulmonary diseases	
and allied conditions	. 110,530
All causes	10,006,060

By comparison, in 1900 tuberculosis, influenza and pneumonia, and diphtheria were the three leading