FDA and Related Tracking Systems Concerned with Sodium

ALLAN L. FORBES, M.D.

SUMMARY The U.S. Food and Drug Administration (FDA) and the Department of Health and Human Services have developed a five-point set of sodium initiatives aimed at moderation of sodium consumption, improved sodium-related information for consumers and health professionals, and improved consumer choice in the marketplace. Implementation is fundamentally based on a voluntary premise, and indications to date are that the program is working. FDA has established a series of tracking systems to measure change over time, particularly relative to changes in the sodium content of the food supply, in the sodium content of American diets, in sodium labeling — both quantitative and qualitative, in consumer understanding of the sodium-and-hypertension problem, and in consumer food purchasing practices. Some of these efforts are conducted in cooperation with other Federal agencies such as the National Heart, Lung, and Blood Institute and the Department of Agriculture. The epidemiological approach to measurement of the prevalence of hypertensive disease as provided by the periodic National Health and Nutrition Examination Surveys is at the center of all other tracking systems to measure effectiveness of the national effort to reduce sodium intakes and thereby hopefully moderate the magnitude and severity of hypertensive disease as a major public health problem in the United States. (Hypertension 4 (supp III): III-170-III-175, 1982)

KEY WORDS • Food and Drug Administration • sodium tracking • epidemiology • federal health programs

T goes without saying that the ultimate control of hypertensive disease depends on continuing inquiry into the fundamental research areas that have formed the framework of this Symposium, i.e., nutritional factors, the basic physiological mechanisms of blood pressure regulation, and genetic and environmental factors. Nevertheless, as sufficient knowledge is acquired in any particular area, it is reasonable to implement programs vigorously to apply this knowledge, recognizing that such efforts are only part of the total approach that ultimately may provide control of the disease well beyond what is now possible. Partial success along these lines has certainly been achieved in recent years through weight control and judicious use of drug therapy. My purpose is to describe another such effort — the sodium initiatives of the Food and Drug Administration (FDA) and the Department of Health and Human Services (HHS) which were started 11 months ago, and to outline the tracking systems put in place to measure the impact of the initiatives.

Sodium Initiatives

These sodium initiatives came about because a clear consensus gradually emerged in the mid- and late-1970s from the biomedical community that it would be reasonable to moderate sodium intakes by the American population. This consensus applied not only to the patient on a sodium-restricted diet because of known hypertensive disease, but also to the general population because of the strong working hypothesis that there is a relationship between sodium intake and the onset and pathogenesis of the disease itself. Key segments of the biomedical community expressing these views are: the American Medical Association (AMA); the Task Force of the American Society for Clinical Nutrition on the Evidence Relating Six Dietary Factors to the Nation’s Health; the Hypertension Task Force of the National Heart, Lung, and Blood Institute (NLBI); the Food and Nutrition Board of the National Academy of Sciences-National Research Council (NAS/NRC); the Select Committee on Generally-Recognized-as-Safe (GRAS) Substances (SCOGS) of the Federation of American Societies for Experimental Biology (FASEB); the Senate Select Committee on Nutrition and Human Needs; and our Department in conjunction with the Department of Agriculture (USDA).

The sodium initiatives themselves consist of five points that were first put forth by U.S. Food and Drug Administration (FDA) testimony on April 14, 1981, before the Subcommittee on Investigations and Oversight of the House of Representatives Committee on Science and Technology, the primary focus of which is moderation of the sodium content of the national food supply through mechanisms fostering increased consumer choice and understanding.
Labeling of Packaged Foods

The first initiative concerns labeling of packaged foods. In the immediate future, FDA will publish a proposal in the Federal Register to amend the food labeling regulations to: 1) establish definitions for the terms “sodium free” (5 mg or less per serving); “low sodium” (35 mg or less per serving); “moderately low sodium” (140 mg or less per serving); and “reduced sodium” (75% or greater reduction); 2) provide for the proper use of these terms in the labeling of foods; 3) provide for the inclusion of potassium content information in the nutrition labeling format on a voluntary basis; 4) provide for the appropriate use of such terms as “without added salt,” “unsalted,” and “no salt added,” and 5) specify that sodium content of foods be included in nutrition labeling information whenever nutrition labeling appears on food labels.

Voluntary Reduction of Salt Content

The second effort involves voluntary reduction in the amount of sodium in processed foods, which to date has involved many discussions between FDA and various segments of the processed food industry — discussions that will continue indefinitely. Results have been very encouraging. For example, General Foods will provide sodium labeling for all of its products containing more than 35 mg per serving. Quaker Oats has introduced sodium labeling on most of its products, and the remainder will be so labeled over the next year. Campbell Soup has undertaken an active program to reduce the salt content of its products, to develop and market a line of “low sodium” soups, and to provide extensive sodium labeling. The Stop-and Shop Supermarkets chain has introduced a no-salt added line of canned vegetables. All Del Monte brand labels will include sodium labeling. In cooperation with FDA, the Food Marketing Institute (FMI), representing the retail food industry, has developed a brochure, Sodium Sense, on moderating sodium intake to be offered in 17,000 retail food stores. All in all, we have met with about 30 different major groups from the industry, including large individual firms and trade associations representing them, each providing a commitment toward moderating the sodium content of processed foods and/or the provision of much more sodium labeling. Collectively, these efforts already involve many billions of dollars of the processed component of the food supply, and we estimate that, for example, the amount of sodium labeling in the marketplace will double or triple over the next year to the point that it will approach 40% or more of the processed food supply in retail sales value terms.

Consumer Education

The third initiative is consumer education. A concentrated effort is now under way in cooperation with the private sector and several other Federal agencies. FDA has published a series of articles in its FDA Consumer magazine. 10, 11 USDA has published an excellent new document providing details of the sodium content of common foods. 12 The National High Blood Pressure Education Program (NHBPEP) of NHLBI has incorporated much of FDA's educational efforts into its broad program, and much of the total Federal effort is now reflected in joint NHLBI-FDA programs. Both of us have worked together with the private sector in developing the previously mentioned FMI brochure, Sodium Sense, and another brochure entitled Straight Talk About Salt, produced by the Salt Institute. 13 FDA and USDA are currently developing another joint publication directed at the consuming public. A series of TV public service announcements are now being widely aired in both English and Spanish, and FDA is now developing a modular television package consisting of videotapes, slides, and script that will enable local television stations to produce half-hour public affairs programs on sodium. Media coverage — press, radio, and television — has been good. HHS Secretary Richard Schweiker, FDA Commissioner Arthur Hull Hayes, and other FDA officials have presented many speeches to professional, industrial, and consumer groups. FDA’s consumer affairs officers all over the country are also intimately involved in the consumer education effort. When the new food labeling regulation is finalized, we will launch another educational effort focusing on teaching consumers how best to use the label information.

Monitoring Events and Changes

Relating to Salt Consumption

The fourth initiative concerns monitoring events in the marketplace and food consumption changes that may occur. This initiative is the principal theme of this talk, to which I will return in a moment.

Enacting New Legislation

The last part of the total effort is possible new legislation. Secretary Schweiker and Commissioner Hayes have made it clear that we are pursuing a program that is almost entirely voluntary, the only exception being the proposal to add sodium to all nutrition labels. However, it is worthy of note that there is considerable interest in the Congress, evident by the introduction of two bills in the 97th Congress and a series of hearings on the subject over the past year. House Bill H.R. 4031, introduced by Congressman Smith of Iowa and strongly pursued by Congressman Gore of Tennessee, would require mandatory sodium and potassium labeling of all foods with greater than 35 mg per serving total sodium and potassium content. The Secretary may grant exceptions for certain foods and for small business. House Bill H.R. 5160, introduced by Congressman Broyhill of North Carolina, would require the Secretary and FDA to continue to develop and implement a voluntary sodium labeling program for appropriate food products. FDA would be required to report to the Congress in 15 and 27 months after enactment on its progress with the voluntary program. If the voluntary program failed, the bill would then allow FDA to ask for mandatory labeling.
Tracking Systems Complementary to FDA Systems

Most federally supported nutrition tracking systems undertaken primarily by agencies other than FDA have been reviewed elsewhere by the author. The totality of nutrition tracking systems has also been addressed in a document transmitted to the Congress on September 28, 1981, jointly by our Department and USDA entitled Joint Implementation Plan for a Comprehensive National Nutrition Monitoring System. The complete monitoring system consists of eight components, each of which can shed light on sodium.

Food Production Surveillance

This continuous system by the USDA generates food disappearance data from which some general inferences relative to sodium content of the food supply can be derived.

Surveillance of Food Composition

Food composition data, including sodium content of individual foods, are derived on a continuous basis from USDA, FDA, industrial and academic laboratories, and are ultimately deposited in the National Nutrient Data Bank managed by USDA.

Food Consumption Surveys

Two large surveys undertaken periodically are USDA's Nationwide Household Food Consumption Survey and the food consumption component of the National Health and Nutrition Examination Surveys (NHANES) conducted by the National Center for Health Statistics (NCHS) of our Department. The most recent of these surveys were conducted in 1977–78 and 1976–1980 respectively. Data from both of these surveys are now being widely used to estimate sodium intakes, and we at FDA have just used them to redesign our FDA Total Diet Study.

Marketplace Surveillance

This is the tracking system FDA uses to measure sodium-related labeling, both qualitative and quantitative.

Clinical Nutrition Examinations

The predominant source of actual clinical nutrition status by physical, anthropometric, and biochemical examinations is the NHANES survey.

Consumer Attitudes and Practices Surveys

These are primarily FDA efforts as they pertain to sodium.

Communications Effectiveness Mechanisms

These in essence are joint efforts by our Department and USDA to coordinate consumer information and education materials concerning nutrition, including sodium, to ensure reasonable consistency and accuracy in the overall messages that the Federal Government is providing to the public.

Methodology Development

These represent the total efforts of the national biomedical and nutrition communities to improve methods of assessment of the nutritional status of individuals and population groups; of measuring food consumption; of analyzing for nutrients, including sodium, in foods, etc.

The fundamental purpose of FDA’s tracking systems concerned with sodium is to monitor changes in the nation's sodium consumption and marketplace practices to determine if FDA’s efforts are meeting the Agency goals of:

1. More sodium information to consumers
2. Less sodium in food
3. More consumer knowledge concerning the relationship between sodium and hypertension
4. Less sodium consumption.

The total tracking or monitoring system consists of:

1. The FDA Total Diet Study
2. The FDA Total Diet Study (FLAPS)
3. Consumer Surveys
4. NHANES.

The FDA Total Diet Study

The Total Diet Study has the general purpose of providing data on the chemical composition of foods representing typical diets for various age-sex population groups. The Study has been conducted for many years for purposes of tracking pesticides, heavy metals, other environmental contaminants, and certain essential nutrients, including sodium and potassium. It is conducted annually and is the only national effort to measure these food components chemically in foods representative of the total national food supply. Relative to sodium, these annual studies provide the principal analytical tool to track changes in the total sodium content in the American diet and to interpret various dietary patterns vis-a-vis sodium content. The same capability pertains to potassium. Collection of individual foods at the retail level for the 1982 survey commenced in March and results for the 1982 study will be available by mid-1983.

The food list and diets used in the Total Diet Study until March 1982 were based on data from the 1965 USDA Household Food Consumption Survey. Each year, approximately 200 foods were collected from each of 30 sites throughout the United States and sent to the FDA Field Office Laboratory in Kansas City where they were prepared for consumption, composited into 11 or 12 food groups, and then analyzed for minerals and contaminants. These 200 foods were specifically selected to represent a subset of the total food supply. The mineral and contaminant content of this food subset was then extrapolated on a food commodity basis to the total diet to allow for estimation of the daily mineral and contaminant intakes of three age-sex groups (teenage males; 6-month old infants; and 2-year
old toddlers). Once the food consumption data from both the 1976–1978 USDA Nationwide Household Food Consumption survey and NHANES-II became available in 1981, we redesigned our Total Diet Study to “modernize” it and to increase its flexibility. Three basic changes have been made:

1. The food lists and diets were updated to reflect as closely as possible the present food supply and current food consumption practices.
2. The number of age-sex groups for primary focus was increased to expand the coverage of the United States population.
3. Foods henceforth are being analyzed individually rather than in composites of commodity groups. This permits estimations of the contribution of specific foods to the intake of minerals and contaminants, as well as a great increase in ability to examine intakes of virtually any age-sex group. In terms of actual data analysis, we will be focusing on infants, young children, male and female teenagers, male and female adults, and male and female older people.

The specific food items in the study have been selected to approximate 90% or more of the weight of the foods consumed by all of the target age-sex groups. Relative to sodium, the results will reflect sodium naturally present, sodium added to commercially processed foods, that added according to package instructions, and that added according to standard recipes. They will not reflect additional discretionary sodium added during cooking or at the table. After aggregation of virtually all foods in the food supply, 234 individual foods were selected for measurement of 11 minerals and over 120 contaminants, representing 100% of the weight and caloric value of average diets, and, as noted, 90% or more of most diets consumed in the United States. Details of the revised study have been put on file with the National Technical Information Service and a condensed version has recently been submitted for publication in the scientific literature.

To summarize some of our recent data, during the 4-year period 1977–1980 (excluding 1979 when sodium and potassium were not measured), sodium content of the daily infant diet ranged from about 700 to 900 mg, and potassium from 1500 to 1700 mg. The toddler diet contained about 1600 to 1800 mg sodium, and 1700 to 1900 mg potassium daily. Sodium content of the young adult diet was approximately 1700 to 1800 mg per 1000 kcal, or when calculated to reflect high total caloric intakes of 3900 kcal, 6700 to 6900 mg. Adult potassium intakes approximated 1200 mg per 1000 kcal or 4600 mg per 3900 kcal diet. On a caloric basis, sodium intakes tended to increase as age increased, whereas potassium intakes tended to decrease. Statistical examination of the data comparing the 3 years of 1977, 1978, and 1980 revealed no significant change in the sodium content of the diet for all three age groups. Considerably more details in the sodium and potassium aspects of the Total Diet Study have been published recently in the literature.

The FDA Food Labeling and Packaging Survey (FLAPS)

The fundamental purpose of the FDA Food Labeling and Packaging Survey (FLAPS) is to track all food labeling information of the total packaged-processed food supply. Relative to sodium, the survey provides quantitative estimates in terms of volume-of-market and retail dollar sales of both quantitative declarations of sodium and qualitative sodium claims. For example, it provides precise information on how much sodium labeling in terms of milligrams per serving actually exists in the marketplace and how this changes over time, as well as similar information on such claims as “low sodium” or “no salt added.” The survey also allows indirect monitoring of changes in sodium content, e.g., the disappearance of salt as an ingredient from a conventional food that previously had salt added. Last, the survey permits measurement of the accuracy of sodium labeling information because the FDA uses the individual food items in the FLAPS study as the basis for its sodium labeling surveillance and compliance programs in which it measures many hundreds of foods for sodium content chemically, in addition to those analyzed in the Total Diet Study.

FLAPS is a biennial survey of a national probability sample of food products. The sample consists of approximately 1700 food brands and is representative of the packaged processed foods sold in grocery stores throughout the United States. The actual sample in the 1979 survey, for example, accounted for approximately 60% of all grocery store sales of $117.8 billion; it does not include fresh meat, poultry, fruits, and vegetables. Included are virtually all shelf-stable, refrigerated, and frozen products, divided into about 200 different product classes representing 50 major processed food groups. All of the label information is recorded, computerized, and analyzed by FDA in terms of the national sales volume of the brands in the sample. The sales information is obtained under contract with the A.C. Nielsen Company. Terms of the contract prohibit disclosure of the actual sales or market position of individual brands or product classes. Hence, for public disclosure purposes, we confine ourselves to aggregated data at the food group level or greater. The third FLAPS study is now under way; sample collection started in February, 1982 and will be completed by June. Approximately 6 months is required to computerize and analyze the data, so the next report should be available in early 1983. Reports of earlier studies are available on request.

To review typical results from FLAPS relative to sodium, an analysis of the 1977 data revealed that approximately 61% of packaged food bearing ingredient labeling contained one or more sodium-containing compounds. Between 1977 and 1979, a highly significant increase in quantitative sodium labeling as part of nutrition labeling occurred, increasing from 7.5% to 13.4% of the packaged processed food sales. This was concentrated in certain food groups such as breakfast cereals, baking mixes, baby foods, salad dressings, flour and refrigerated breads, pastries, and spreads. As
pointed out earlier, based on commitments by many major food firms and trade associations, the FDA is projecting that the amount of sodium labeling will double or triple over the next year, approaching 40% or more of the packaged processed food supply.

FDA Consumer Surveys and Studies

Information relative to sodium is generated through several different types of consumer studies. Perhaps the most important are the FDA's periodic so-called Multipurpose Consumer Surveys wherein it explores consumer perceptions, knowledge, and purchasing practices concerning foods and nutrition. This approach permits measurement of the impact of public education campaigns and labeling initiatives on buying habits and understanding. These surveys are conducted using telephone survey techniques to reach national probability samples of food shoppers, and generally are conducted annually. To date, the FDA has not concentrated on sodium-related issues, but its 1978 survey did reveal that salt was second only to sugar among food ingredients that food shoppers attempted to avoid (13.1% stated that they deliberately tried to avoid salt-containing foods). However, the current FDA survey will concentrate very heavily on sodium, salt, and hypertension to build a comprehensive baseline of consumer understanding of the issues, for purposes of tracking change over time. This year's survey is being undertaken in collaboration with the NHLBI and will involve a national probability sample of 4000 households. The 40-minute telephone questionnaire is currently being developed, and plans call for the field work to be undertaken over a 60-day period during the summer of 1982, with completion of data analysis by the end of 1982. Particular attention will be paid to consumer understanding of the relationships between salt and high blood pressure, high blood pressure and the word "hypertension," salt and sodium, reasonable levels of sodium in the total daily diet, ability to understand sodium-related label information, and the sodium content of common foods. About two-thirds of the 1982 survey will be devoted to these issues. All of these types of surveys permit reasonable interpretations in major demographic terms such as sex, educational level, geographic location, etc.

Another approach related to sodium and hypertension is a recently completed study of the opinions of professional nutritionists (members of the American Institute of Nutrition (AIN)), representatives of the food industry, and consumer groups. All three groups identified obesity and heart disease as the major diet-related national health problems, and chose as most useful to the public information about calories, sodium, fat, protein, iron, calcium, and carbohydrates. For example, when asked to identify and rank order the seven most useful types of nutrient information, calories came first, with 93% of AIN members stating it to be in the top seven, 93% of food industry representatives, and 84% of consumers. For fat, the percentages were 60%, 70%, and 62% respectively, and for sodium 57%, 58%, and 68% respectively. The striking point of the entire study was the high level of agreement between these three segments of society that are often alleged to have conflicting views on nutrition-related matters generally.

A third approach is incorporation of sodium-related questions in special studies. For example, the FDA recently completed a national survey of use of dietary supplements, and anticipate completion of the report by the end of the summer. Preliminary results indicate that about one-quarter of all adult age groups have recently made changes in their use of table salt for cooking and/or at the table, practically all of which refers to using less salt; about 10% are trying to limit the use of salt to a specific amount per day, and slightly fewer are avoiding the use of added salt all together.

Lastly, the FDA has a collaborative 2-year study under way with a supermarket chain (Giant Food, Inc., Washington, D.C.) to study the impact of sodium labeling, including "shelf talkers" and fliers providing descriptive information on actual consumer purchase behavior. The FDA is tracking the weekly sales of approximately 100 foods in a sample of Washington, D.C. and Baltimore, Maryland stores. The Washington stores are serving as the experimental group, with various approaches being used to focus attention on sodium labeling and sodium-modified foods, and the Baltimore stores are serving as controls, where no sodium-specific program is in place. The study commenced in March, 1981, and data analysis for the first year is planned for this summer and early fall. The commodity groups under study include canned and frozen vegetables, pasta products, nuts, snacks, salad dressings, desserts, bread, crackers, breakfast cereals, butter, margarine, and various beverages.

Health and Nutrition Examination Survey

To quote from a paper I presented at last year's annual meeting of the Institute of Food Technologists:

"The fundamental core of any nutrition monitoring system is measurement of actual clinical nutrition status by physical, anthropometric, and biochemical examination, i.e., the NHANES survey. We are way past the point of being able to rely on food consumption data to estimate nutritional status. Given the current state of the art, there is simply nothing that can replace statistically sound medical evaluation. If further austerity is necessary in activities concerned with nutrition monitoring, I very much hope that budget cuts would be directed at activities other than NHANES, without which we will not know what is happening to the nutritional health of Americans at a time when there are many factors that can profoundly affect nutritional health." I strongly adhere to these concepts.

As I'm sure all of you know, a great deal of our knowledge on the prevalence and severity of hypertension in the United States is derived from the periodic NHANES surveys. This is illustrated by the April, 1981 publication Hypertension in Adults 25-74 Years of Age from NCHS, based on data from NHANES-I conducted in 1971-1975. Key conclusions were that an estimated 18.0% of civilian noninstitutionalized
adults in the U.S. 25–74 years of age had definite hypertension (160 + mm Hg systolic and/or 95 + mm Hg diastolic); the prevalence reached 34.2% for adults 65–74 years of age; hypertension is about twice as prevalent among blacks as among white adults; about one-fourth of the adults with definite hypertension have elevated diastolic pressures of at least 105 mm Hg; and nearly one-half of the adults with definite hypertension have never been told by a doctor that they had high blood pressure.

The FDA and many other groups around the country are now actively working with the data tapes from NHANES-II undertaken in the field 1976–1980, as the tapes become available. NHANES-II was conducted in a nationwide probability sample of approximately 28,000 persons, aged 6 months through 74 years, from the civilian noninstitutionalized population of the United States. The survey started in February, 1976 and was completed in February, 1980. The NHANES-II sample was selected so that certain population groups thought to be at high risk of malnutrition (persons with low incomes, preschool children and the elderly) were oversampled. Adjusted sample weights were then computed for 76 age, sex, and race categories in order to inflate the sample in such a manner as to closely reflect the estimated civilian noninstitutionalized U.S. population aged six months through 74 years at the midpoint of the survey (March 1, 1978). Details of the plan and operation of NHANES-II have been published.15 Also, guidance documents on the use of individual data tapes are made available as each tape is released, e.g., the specific food item tape for the 24-hour recall of food consumption.16 It is our understanding from NCHS that the data tapes of the clinical examinations from NHANES-II, including blood pressure measurements, are scheduled to be available in July, 1982, and that NCHS intends to publish the blood pressure data within calendar year, 1982.

To facilitate and accelerate data processing and interpretation from NHANE-II, FDA and NCHS have established an ad hoc NHANES-II Users Group — an informal group of individuals from academia, industry, and government agencies who are actively working with the data. The purposes of the group are threefold: 1) to promote communication and data exchange; 2) to limit unnecessary duplication of effort; and 3) to track NHANES-related research and publications. The group first met in November, 1981, met again in March, 1982, and will assemble again in early fall.

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A L Forbes

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