IOM Urges Feds to Lower Sodium Content in Foods

BY ELIZABETH MECHCATIE

A report by the Institute of Medicine recommends changing federal standards to require a marked reduction in the amount of sodium that can be added to food by manufacturers, restaurants, and food service companies.

The report on strategies to reduce sodium intake recommends an incremental stepwise approach that would gradually reduce sodium content to allow people to become accustomed to lower sodium levels in food.

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The IOM, citing an "urgent public health problem," says the daily value for sodium should be 1,500 mg/day.

Excessive dietary sodium intake in the United States is an "urgent public health problem," Dr. Jane E. Henney, chair of the committee that wrote the report, said during a briefing held by the IOM.

The report's main recommendation calls for the Food and Drug Administration to set mandatory standards for the safe levels of sodium that is added to food, utilizing the agency's authority to modify the current "Generally Recognized as Safe (GRAS)" status of salt and other sodium-containing compounds.

The report also suggested that maximum levels be established for salt and other sodium-containing compounds "that will allow people to consume a normal diet with a reasonable likelihood of keeping their sodium intake to recommended levels," Dr. Henney added.

Reducing sodium intake has the potential to prevent 100,000 deaths per year and save billions in health care costs, she said. While a certain level of sodium intake is safe, the amount consumed by the average person in the United States is "far beyond" the essential levels needed, noted Dr. Henney, professor of medicine at the University of Cincinnati.

People in the United States consume an average of more than 3,400 mg of sodium a day (the amount in about 1.5 teaspoons of salt), which is about 50% higher than the recommended maximum recommended intakeof 2,300 mg for adults (the amount in about 1 teaspoon of salt).

Because the use of a maximum level of intake can be mistakenly perceived as a desirable amount, the report recommends that the daily value for sodium be changed to 1,500 mg per day, which is the adequate intake for adults.

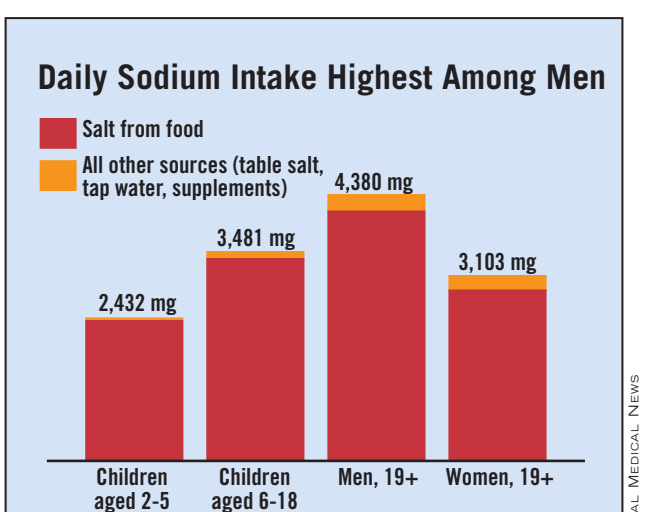
Dr. Henney said that the FDA should "expeditiously" start the process of rule making that will be needed to change the amount allowed in food, which is a long process.

A statement issued by the FDA in response to the release of the IOM report said that the agency plans to review the report's recommendations and will "build plans for how the FDA can continue to work with other federal agencies, public health and consumer groups, and the food industry to support the reduction of sodium levels in the food supply."

In addition, an interagency working group on sodium will be established by of the Department of Health and Human Services.

The IOM report, done at the request of Congress in 2008, was sponsored by the FDA; the Centers for Disease Control and Prevention; the National Heart, Lung, and Blood Institute; and the Office of Disease Prevention and Health Promotion at HHS. ■

The report is available at www.iom.edu/Reports/2010/Strategies-to-Reduce-Sodium-Intake-in-the-United-States.aspx.



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House Inquiry on Heparin

Two House Republicans are seeking more information from the Food and Drug Administration on its investigation of contaminated heparin from China. Joe Barton (R-Tex.) and Michael Burgess (R-Tex.), each a ranking minority member on a powerful health panel, said their investigators have uncovered new information that "warrants further review of Chongqing Imperial for direct involvement in, or knowledge about, the contamination of heparin." In a letter to FDA Commissioner Margaret A. Hamburg, the House members said that the FDA has not "adequately" followed up on pertinent evidence and asked Dr. Hamburg to respond.

Device Claims Called Illegal

The FDA has warned device maker St. Jude Medical about illegal promotion of its Epicor LP Cardiac Ablation System and Epicor UltraCinch LP Ablation Device. A Web site aimed at physicians claimed that the Epicor LP system could "create the critical Cox Maze III lesions entirely epicardially" and that the UltraCinch device could "safely, effectively and reproducibly create a classic box lesion in a single step." These amount to unapproved claims for treatment of atrial fibrillation, the FDA stated in its letter. Also, sales reps were giving presentations to physicians that promoted use of the devices for atrial fibrillation, the agency claimed. It asked St. Jude to cease and desist. By press time, the cited Web site had been taken down.

AARP Tallies Big Drug Price Rise

The AARP said that brand name prescription drug prices rose almost 10% in the year ended March 31, compared with a 0.3% rise in general inflation over the same period. The seniors' advocacy group said that the increase for the 25 brand-name drugs prescribed most often to Medicare beneficiaries for chronic conditions was the largest since the organization began tracking such data in 2002. The report said that prices for a sample of generic drugs declined by about 10% over the same period. Prices of specialty drugs rose by about 9%. That was less of an increase than in the 3 previous years. Pharmaceutical Research and Manufacturers of America Senior Vice President Ken Johnson said in a statement that the report is "based on incomplete information" because prices don't take into account discounts and rebates.

New Tobacco-Science Chief

The FDA has named a director for the Office of Science within its new Center for Tobacco Products. Dr. David L. Ashley will assume the position sometime this month. Currently, he is the chief of the Emergency Response and Air Toxicants Branch of the Centers for Disease Control and Prevention. Dr. Ashley also is a member of the World Health Organization's study group on tobacco regulation. At the new center, he will oversee science, product review, epidemiology and metrics, and social and behavioral sciences, according to the FDA.

Billions Wasted on Medications

Americans are wasting $163 billion a year on medications, primarily because of lack of adherence to prescriptions, the pharmacy-benefit management company Express Scripts estimates. The company came up with its tally as part of its annual report on drug spending. In 2009, $106 billion in waste was caused by nonadherence, $51 billion by failure to use lower-cost alternatives, and $6 billion by people choosing retail over mail-order delivery, said Express Scripts, which has a mail-order subsidiary. The biggest two areas of waste are in treating high cholesterol and hypertension. The company said that 35% of the annual spending on lipid medications could be saved if people behaved better.

Providers Asked to Find 'Bad Ads'

The FDA has launched a program to get health care providers to detect and report misleading drug ads. The "Bad Ad" program seeks to educate health care providers about their role in ensuring that prescription drug advertising is truthful and not misleading, the agency said. Initially, FDA officials will meet with providers at selected medical conventions and will partner with a handful of medical groups to distribute educational materials. The agency said it will then expand its collaborations with medical societies. The announcement encouraged health care professionals to report any potential violation in drug promotion by sending an e-mail to badad@fda.gov.

FDA Proposed New Ad Rules

The FDA wants manufacturers to detail more of the contraindications and potential side effects of drugs in radio and television direct-to-consumer advertisements. The proposed rule would require that an ad's major statement on side effects and contraindications "be presented in a clear, conspicuous, and neutral manner." The new rule would require manufacturers to present the information in both the audio and visual components of a video ad and make sure that it is not overshadowed by other parts of either type of ad. The FDA said it will accept comments on the proposed rule until June 28.

—Alicia Ault