



DEPARTMENT OF HEALTH & HUMAN SERVICES

HFA-305

Food and Drug Administration
Rockville MD 20857

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July 29, 2004

NOTE TO DICK EISENGER OS/ES:

Subject: Correspondence from George A. Bray, MD, commenting on the Food and Drug Administration's (FDA) report, "Calories Count"
(OS # 07270440015/FDA trac #04-4142) -- CLOSE OUT

This letter comments on FDA's obesity report, "Calories Count" (FDA Docket No. 2003N-0338). We have sent this letter (copy) to our Dockets Management Branch to log in as a comment on the report, which is the standard procedure for handling comments. We do not intend to respond since any comments received are being addressed. Thank you.

Indya Mungo
Policy Analyst
FDA Executive Secretariat

Attachments

cc:
Elaine Gross, OS/CCC
HFA-305

2003N-0338

C20/ANS

04-4142

G:\Wp\INDYA\George Bray.DOC

Drafted:IMungo:7/29/04

Reviewed:Pwilliams:7/29/04

**ROUTING SLIP
GENERATED BY: HF-40
DATE: JUL 29, 2004**

FDA CONTROL NUMBER: 04 4142

TRACER #: OS #: 0727040015

DATE OF CORRESPONDENCE: 07/22/04

DATE INTO FDA: 07/29/04

TO: TOMMY G THOMPSON, SECRETARY, HEALTH AND HUMAN SERVICES

FROM: GEORGE A BRAY, MD, LOUISIANA STATE UNIVERSITY - PENNINGTON BIOMEDICAL RESEARCH CENTER

SYNOPSIS: SWIFT D/R - FORWARDS COMMENTS ON FDA'S "CALORIES COUNT" DOCUMENT ON OBESITY STUDIES; INCLUDES BOOK "CONTEMPORARY DIAGNOSIS AND MANAGEMENT OF OBESITY AND THE METABOLIC SYNDROME."

LEAD OFFICE: HF-40

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COPIES: HF-1 LESTER M CRAWFORD
HF-1 SUSAN E MACKIE BOND
HF-40 INDYA G MUNGO
HFS-1

COORDINATION:

SIGNATURE REQUIRED:

REFERRALS FROM HF-40

ASSIGNED TO	ACTION	DUE DATE
----- HF-40 WILLIAMP	----- PREPARE DIRECT REPLY	----- 08/11/04

Secretary's Correspondence

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF THE SECRETARY
EXECUTIVE SECRETARIAT

From: **George A. Bray** *OS#:* **072720040015**
Organization: **Pennington Biomedical Research Center** *Date on Letter:* **7/22/04**
City/State: **Baton Rouge LA** *Date Received:* **7/27/04**
On Behalf Of: *Type:* **General Public**
Subject: **Forwards comments on FDA document on obesity studies. Also includes his book 'Contemporary Diagnosis and Management of Obesity and The Metabolic Syndrome'**

Assigned to: **FDA** *Dep.ES:* **Dick Eisinger**
PC: **Tom Kuchenberg** *Date Assigned:* **7/28/04**
Action Required: **Direct Reply** *Date Reassigned:*
Reply Due Date: **8/11/04**

Info Copies To: **SWIFT, OPHS**

Interim (YIN): **No** *Date Interim Sent:*

Comments:

File Index: **PO-4** *CCC:* **Elaine Gross**

07-29-04 A08:32 RCVD

07/27/04

*** RECEIVED ***
Jul 27, 2004 12:13:49 WS# 06
OFFICE OF THE SECRETARY
CORRESPONDENCE
CONTROL CENTER

ENCLOSURES

WERE NOT SCANNED

ENCLOSURE TYPE: Book
2004072712134906 George Bray

PACKET TO BE
DELIVERED MANUALLY



Pennington Biomedical Research Center
LOUISIANA STATE UNIVERSITY

July 22, 2004

Honorable Tommy Thompson
Secretary, The U.S. Department of Health and Human Services
200 Independence Avenue S.W.
Washington, D.C. 20201

RECEIVED
04 JUL 27 AM 10:42
OFFICE OF THE SECRETARY
COMMUNICATIONS
CONTROL CENTER

Dear Secretary Thompson:

Re: Progress in the War on Obesity

Thank you for making obesity such a high priority for the Department of Health and Human Services. Through your efforts there has been great progress, but there is still a long way to go before you can claim victory. The recent pronouncements by the Medicare Agency that "obesity can be considered a disease" is a major milestone. As a token of my esteem for your work, I am enclosing a copy of a small monograph on obesity written to educate medical students, physicians and health care workers entitled *Contemporary Diagnosis and Management of Obesity*.

Before going further, let me introduce myself. I am George A. Bray, M.D., University Professor at the Pennington Biomedical Research Center of the Louisiana State University System in Baton Rouge, LA. I have worked in obesity for 40 years and have been continuously funded by the NIH during all that time. I chaired the first Fogarty Center/NIH Conference on Obesity in 1973, organized the *International Journal of Obesity* in 1975, founded the North American Association for the Study of Obesity (NAASO) in 1980, and founded and acted as first editor for *Obesity Research*, the official Journal of NAASO.

During these years I have watched with horror as the epidemic has spread, particularly to the children and youth. In spite of well-meaning educational activities by NIH and DHHS in the past the epidemic has occurred and continues to grow.

"Calories Count" is the title of a recent document from the FDA that outlines their plans to tackle this problem. Their publication prompted this letter. In a separate letter, I am sending them a page-by-page critique because what they are trying to do is so important, and I thought my long experience in the field might be of some value to them.

The title "Calories Count" is, to quote from the report, "centered on the scientific fact that weight control is primarily a function of balance of the calories eaten and calories expended on physical and metabolic activity". While this

restatement of the First Law of Thermodynamics is absolutely true, it is largely irrelevant. My analogy is with the laws of motion. The greater the momentum of an object (an automobile) the greater the kinetic energy that is released when it collides with an immovable object (an automobile crash). While true, we have alternative routes to providing safety for automobile drivers. We have used education, regulation, and product design.

One serious implication of the "Calories Count" concept is that all we need to do to conquer obesity is "to count calories". Eat less and exercise more. If you don't do this, it is your fault that you are obese. Although many people view obesity as a problem of "weak will power," which would not occur if people pushed themselves away from the table, such an attribution is unfair for our children. Do we want to blame them for being obese? I hope not.

The strategies of education, regulation and product design that have been useful in reducing automobile accidents resulting from the laws of motion may be useful in dealing with the problem of obesity resulting from the Laws of Thermodynamics. The FDA document proposes an educational program around the idea that "Calories Count." These have shown no success in the past, and it would be disingenuous to think they will work in the future. An educational program aimed at healthy weight or healthy eating might be a more productive educational objective.

For regulation, the FDA document talks about rationalizing the nutrient label on foods and increasing awareness of portion size. There is no doubt that portion control as a surrogate for calories can be useful in treatment. Whether it could be useful for prevention has not been established.

Product design was little discussed by the FDA document, possibly because they have less involvement with food, in spite of their name, Food and Drug Administration. It is clear to me that the modifications of the food supply will be an essential component of the battle against obesity. As an analogy I note the impact of fluoride in the fight against dental disease. There are at least two strategies for fighting dental disease. The first I call the "Tooth Brush Strategies". If people faithfully brushed and flossed their teeth, tooth decay would be significantly reduced. However, the second strategy, which I call the "Fluoride Strategy," has been much more successful. The addition of fluoride to the water supply was much more effective than brushing teeth and has led to a marked decrease in dental disease.

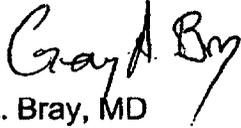
The incorporation of high fructose corn syrup into the food supply occurred just at the time that the epidemic of obesity was beginning and its use in the food supply rose along with the epidemic. This could simply be coincidental, but it could also be stimulating intake of larger amounts of soft drinks and reconstituted fruit drinks with the attendant increase in energy intake. The rise in fried potato consumption to the point where it is now the largest amount of consumed

vegetables may be another component. For your campaign against obesity to be successful will require some novel and innovative approaches to changes in the design of the food supply, including quantity and quality.

Although the First Law of Thermodynamics (energy balance) is no doubt true, it is what it does NOT tell us that is important. It does not tell us why men eat more, but have less fat than women. It does not give any insight into the genetic factors in obesity. It does not help us understand why some drugs cause weight gain and others weight loss. Yet it is in understanding these events and applying that understanding to education, regulation, and product design that we will win the battle of the bulge.

My best to you and the DHHS as you continue the battle of the bulge.

Sincerely,

A handwritten signature in cursive script that reads "George A. Bray". The signature is written in black ink and is positioned above the typed name.

George A. Bray, MD
Boyd Professor

Encl: *Contemporary Diagnosis and Management of Obesity and the Metabolic Syndrome*