
Starvation Diet: FDA Lacks Adequate Resources for its Nutritional Health and Consumer Protection Missions

Center for Science in the Public Interest

Washington, D.C.

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This report was prepared by Ilene Ringel Heller, senior staff attorney, and was edited by Bruce Silverglade, director of legal affairs, and by Michael F. Jacobson, Ph.D. executive director. Joleen Okun, research assistant, and Aliza Sperling, staff attorney, contributed to this report. CSPI wishes to thank Vanessa Serrao Hiemenz for designing and formatting this report. This report was completed in October 2003.

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EXECUTIVE SUMMARY

The Food and Drug Administration's (FDA) Office of Nutritional Products, Labeling, and Dietary Supplements (ONPLDS) is responsible for numerous essential public health and consumer protection programs ranging from ensuring the quality of infant formula to making sure that ingredient and nutrition information on food packages is honest and accurate.

Despite the key role that ONPLDS plays in protecting the health and well-being of all Americans, the Office's resources in terms of full-time equivalent (FTE) staff members at headquarters (excluding staff working on dietary supplement issues) has significantly *declined by more than half over the last decade*.

This reduction in staff is all the more significant considering that the responsibilities of ONPLDS have greatly increased over the same time period. As a result of changes in the law, marketing trends, and new technologies, the Office has been forced to take on entirely new responsibilities, such as approving health claims, reviewing the appropriateness of requirements for standardized foods, monitoring food labeling claims on the Internet, and grappling with entirely new product categories such as functional foods.

To effectively accomplish its mission, ONPLDS' budget should be increased by \$30 million phased in over the next three fiscal years. The investment of this relatively small amount, less than 2% of FDA's current budget, could yield health and economic benefits that would save many more millions of dollars per year in terms of reduced health care expenditures and improved productivity. Thus, even in a time of budget deficits, increasing ONPLDS' budget by this amount to obtain benefits that are substantially greater would be justified. If necessary, Congress should shift funds away from programs that produce fewer public benefits relative to government expenditures and provide ONPLDS with the funding it needs to accomplish its mission.

INTRODUCTION

The Food and Drug Administration's (FDA) Office of Nutritional Products, Labeling, and Dietary Supplements (ONPLDS) is responsible for numerous essential public health and consumer protection programs. These programs include:

- ensuring that foods are honestly labeled;
- guaranteeing the quality of infant formula;
- regulating dietary supplements;
- enforcing standards for medical foods used by hospital and nursing home patients, as well as foods for special dietary use purchased by diabetics, consumers with allergies, and others with sensitive medical conditions;
- promoting the nutritional well-being of all Americans by conducting research on the nutritional status of the American population;
- providing FDA with clinical expertise to help ensure that nutrients in fortified foods are consumed in safe amounts;
- verifying that the ingredient lists and the Nutrition Facts labels on hundreds of thousands of packaged foods are accurate;
- approving new health and nutrient content claims that appear on food labels;
- determining the minimal amount of key ingredients in standardized foods ranging from mayonnaise to frozen cherry pie and;
- assessing whether the percentage of particular ingredients needs to be disclosed to prevent consumer deception.

The purpose of this report is to ascertain how resource limitations are affecting ONPLDS' ability to fulfill its responsibilities. Given the importance of those responsibilities, it is essential that ONPLDS receives adequate funding to accomplish its mission.

Part I of this report will specifically review each major aspect of ONPLDS' responsibilities and discuss the degree to which resource limitations are affecting the Office's ability to fulfill its mission. FDA, in response to a request from Congress,¹ has

¹ The House of Representatives Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration and Related Agencies had asked FDA for a detailed assessment of how much it would cost to implement ONPLDS' Strategic Plan (10 Year Plan) for the Dietary Supplement Health and Education Act (DSHEA). On May 29, 2002, FDA presented Congress with a "cost out" for implementing DSHEA, which estimated that ONPLDS would need from \$90 million to \$160 million over a five-year period. *Dietary Supplement Strategic Plan Cost Out*, available at <http://www.cfsan.fda.gov/~dms/ds-stra2.html> [hereinafter *Cost Out*]. This report will not duplicate FDA's detailed breakdown of the sums it needs to implement DSHEA.

recently completed a detailed assessment of the additional resources it needs to effectively accomplish its mission in the area of dietary supplements.² Because this information has already been submitted to Congress, this report will focus on estimating the amount of additional resources that ONPLDS needs to fulfill other aspects of its mission.

Part II of this report will examine a number of emerging issues related to scientific and technological developments, changes in the law, marketing trends, and other factors that are likely to tax ONPLDS' resources to an even greater extent in the future and further undermine its ability to fulfill its mission of protecting consumer health.

Part III of this report analyzes the Office's workload in terms of pending rulemaking petitions and proceedings and discusses the impact of budgetary shortfalls on the Agency's ability to take timely action on those matters. Part III also evaluates the impact of budgetary shortfalls on ONPLDS' ability to enforce the law, and reviews the impact of this problem on consumers and the food industry.

Part IV of this report documents the decline of resources over the last decade. This report concludes that without a phased in budget increase of \$30 million over the next three years, ONPLDS will be unable to administer adequately the provisions of the Federal Food, Drug, and Cosmetic Act (FDCA) for which it is responsible.

² Following a critical report by the Inspector General for the Department of Health and Human Services, Congress gave FDA additional funding to improve its adverse event reporting system and enforcement capabilities for dietary supplements. Department of Health and Human Services, Office of Inspector General, *Adverse Event Reporting for Dietary Supplements* ii (OEI-O1-00180 April 2001).

