DATA DIGEST

DIETARY SUPPLEMENTS AND OLDER CONSUMERS

INTRODUCTION

Over the past decade, sales of dietary supplements (vitamins, minerals, botanicals [herbal products], and other specialty products[1]) have grown substantially—from $8.8 billion in 1994 to $15.7 billion in 2000.[2] This growth has been attributed to a number of factors, including enactment of the Dietary Supplement Health and Education Act (DSHEA) of 1994,[3] which made it easier to market dietary supplements with attractive claims, and the growth of the self-care movement, which has resulted in consumers taking greater responsibility for their health and health care. While many consumers regularly have taken vitamins and minerals for years, the use of herbal products, once relatively limited, has gained wider acceptance.

With broader use of a wide variety of dietary supplements has come greater concern about the safety and quality of these products.[4] Some dietary supplement ingredients are unsafe for all consumers,[5] while others should not be taken by certain segments of the population (e.g., children, elderly persons, pregnant women, and persons suffering from particular diseases).[6] Of particular concern for older users are possible interactions between dietary supplements and prescription medicines.[7] In addition, poor manufacturing practices can result in products being contaminated with toxins, metals, or pesticides,[8] and in products containing too little or too much of key ingredients.[9]

Furthermore, since dietary supplements are not required to undergo premarket approval for safety and efficacy, the U.S. Food and Drug Administration (FDA), the federal agency that regulates dietary supplements, relies on its "adverse event" reporting

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[1]The term, "specialty products," includes a range of supplement products that are not vitamins, minerals, or herbal products. These include hormones (like melatonin), animal products (like bee pollen and shark cartilage), and other substances (like glucosamine condroitin). Supplements come in many different forms: they are sold as tablets, capsules, powders, softgels, gelcaps, and liquids. 21 U.S.C. Sec. 350(c)(1)(B)(i).

[2]Robert J. Blendon et al. (2001). Americans' Views on the Use and Regulation of Dietary Supplements. *Archives of Internal Medicine*, Vol. 161, p. 805.

[3]Pub. L. No. 103-417. Among other things, DSHEA established new safety standards for supplements, provided for claims and related statements on product labels, and required ingredient and nutrition labeling.

[4]*Health Products for Seniors: "Anti-Aging" Products Pose Potential for Physical and Economic Harm,* (GAO-01-1129, September 2001), pp. 7-11.

[5]For example, the FDA has issued general warnings for herbal products containing aristolochic acid (*see* <http://www.cfsan.fda.gov/~dms/ds-bot.html>) and comfrey (*see* <http://www.cfsan.fda.gov/~dms/dspltr06.html>).

[6]For example, ginseng is not recommended for persons with hypoglycemia, and kava kava may worsen symptoms of Parkinson's disease. *"Anti-Aging" Products*, *supra* note 4, at 8.

[7]For example, ginkgo biloba acts as a blood thinner, so it should not be taken with other blood-thinning agents, such as coumadin, and St. John's wort may decrease the effectiveness of HIV drugs. *See id* at Appendix II.

[8]*"Anti-Aging" Products, supra* note 4, at 10. For example, in 1997, the FDA found that certain dietary supplements were contaminated with *Digitalis lanata*, a plant that contains powerful stimulants and, under certain circumstances, may lead to cardiac arrest. Office of Inspector General (OIG), Department of Health and Human Services, *Adverse Event Reporting for Dietary Supplements* 7 (April 2001).

[9]Herbal Rx: The promises and pitfalls. (March 1999). *Consumer Reports*, Vol. 64, No. 3, p. 44.

system[10] to identify safety problems. However, through the existing reporting system, the FDA learns of less than one percent of adverse events involving supplements, and it fails to investigate most adverse event reports it does receive.[11]

Under DSHEA, dietary supplement labels are required to include a "Supplement Facts" panel that lists all ingredients. Like conventional foods, supplement labels can also include "health claims"[12] that have been preapproved by the FDA. In addition, labels for dietary supplement products can include "structure/function claims,"[13] which do not have to be preapproved by the FDA, as long as supplement labels also include the following disclaimer: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

[10]An "adverse event" is an incident of illness or injury that *may* be associated with a dietary supplement product or ingredient. The FDA receives reports on adverse events from various sources: its medical products reporting program ("MedWatch"), Poison Control Centers, FDA District Offices, State Health Departments, and direct contact with individuals. The FDA also learns about problems with dietary supplements through medical journals and foreign sources.

[11]OIG Report, *supra* note 8, at ii, 1.

[12]"Health claims" describe the relationship between a substance and a specific disease. *See* 21 U.S.C. Sec. 101.14(a)(1). These include claims that link: 1) calcium consumption to a reduced risk of osteoporosis, and 2) consumption of folate to a reduced risk of neural tube defects.

[13]"Structure/function claims" may 1) claim a benefit related to a nutrient deficiency disease (like vitamin C and scurvy), as long as the statement also tells how widespread such a disease is in the United States; 2) describe the role of a nutrient or dietary ingredient intended to affect a structure or function in humans (e.g., "calcium builds strong bones"); 3) characterize the means by which a nutrient or dietary ingredient acts to maintain such structure or function (e.g., "fiber maintains bowel regularity"); or 4) describe general well-being from consumption of a nutrient or dietary ingredient. *See* 21 U.S.C. Sec. 101.93(f).

METHODOLOGY

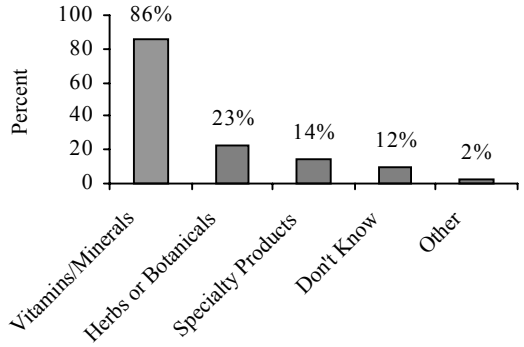
This Data Digest presents results from a nationwide random digit-dial (RDD) telephone survey of 1,480 persons age 50 and older conducted between September 7 and 9, 2001, by RoperASW, Princeton, NJ. The survey's margin of error is plus or minus 2.5 percent. Respondents were asked an array of questions related to their use of dietary supplements as well as their understanding of, and priorities for, government regulation of these products.[14]

FINDINGS

Supplement Use

The survey found that 59 percent of respondents use dietary supplements at least once a month, and an additional three percent use them less frequently. More than half of all respondents (52 percent) indicated that they take supplements daily. Of all respondents who take supplements, 86 percent said that they take vitamins and minerals, 23 percent take herbal products, and 14 percent take "specialty products"[15] (Figure 1).

Figure 1
Types of Dietary Supplements Used
(50+ population)



Source: AARP 2001 Survey on Dietary Supplements
Prepared by AARP Public Policy Institute

More than three-quarters (78 percent) of the

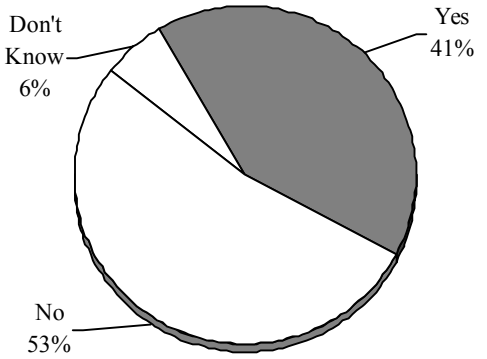
[14]The annotated survey questionnaire accompanies this Data Digest.

[15]*See supra* note 1.

respondents who are supplement users said they take these products to promote overall good health, while 52 percent said they take them to provide nutrients missing in their diets. More than one in four supplement users (27 percent) said they take supplements to prevent a particular disease, and 39 percent indicated they are taking dietary supplements because their doctor or health care provider recommended them.

Only 41 percent of all respondents (those who do and do not use supplements) said they have discussed taking dietary supplements with their doctor, while more than half (53 percent) said they have never discussed this issue with their doctor (Figure 2).[16]

Figure 2
Discussion of Dietary Supplements with Doctor (50+ population)



Source: AARP 2001 Survey on Dietary Supplements
Prepared by AARP Public Policy Institute

Of those who did talk about supplements with their doctor, 18 percent checked with their doctor before deciding to take a particular supplement, and another 15 percent said they told their doctor once they started taking a supplement to learn about any side effects or drug interactions. By contrast, 21 percent indicated their doctor asked if they were using any supplement products.

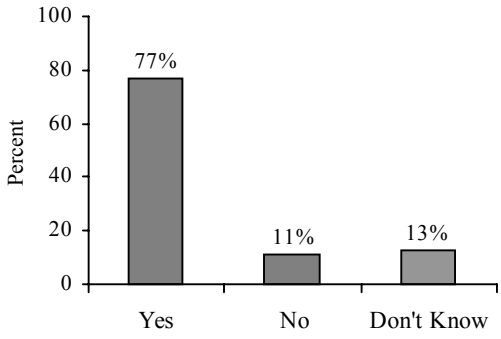
[16]Interestingly, there was a significant difference in responses to this question by male and female survey participants: women (46 percent) were more likely than men (36 percent) to discuss taking dietary supplements with their doctor.

Safety

Large majorities of respondents (both users and non-users of supplements) said the following types of information, not currently required, should be included on supplement labels: information about possible side effects or adverse reactions (82 percent); the maximum amount of the product that is safe to take (81 percent); and information about interactions between supplements and prescription and over-the-counter drugs (80 percent).

The survey also found substantial support for government review of safety data for supplement products. More than three in four (77 percent) respondents (both users and non-users of supplements) think the federal government should review safety data for a dietary supplement product and approve the product before it is sold to consumers (Figure 3).

Figure 3
Should the Federal Government Review and Approve Dietary Supplements Prior to Sale? (50+ population)



Source: AARP 2001 Survey on Dietary Supplements
Prepared by AARP Public Policy Institute

As noted above, the FDA learns of safety problems linked to supplement products through its adverse event reporting system. Only a small proportion of respondents (13 percent) said they would notify the FDA if they had an adverse reaction to a supplement. By contrast, a majority indicated they would stop using the supplement product (78 percent) or contact a doctor or other health care professional (64 percent).

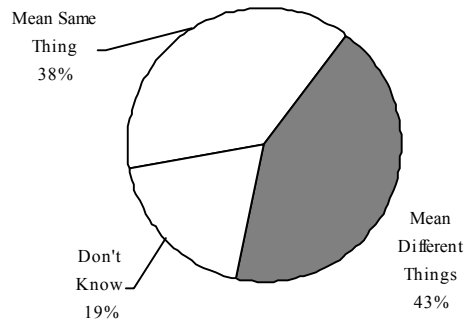
More than three in four respondents (76 percent) supported including information on supplement labels about whom to contact in case of an adverse reaction.

Labeling and Advertising

In addition to the safety information noted above, respondents indicated strong support for including the following types of information on supplement labels: the expiration date (82 percent), the recommended dosage (81 percent), and information on why the supplement is taken (76 percent).

The survey also revealed that a majority of respondents were unable to distinguish between two types of claims: "calcium reduces the risk of osteoporosis" (a health claim) and "calcium builds strong bones" (a structure/function claim). More than half (57 percent) either thought the two claims meant the same thing or they did not know (Figure 4).

Figure 4
Ability to Distinguish "Health" from "Structure/Function" Claims for Calcium (50+ population)

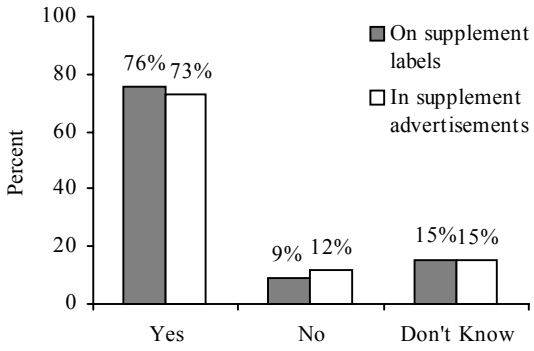


Source: AARP 2001 Survey on Dietary Supplements
Prepared by AARP Public Policy Institute

Seventy-six percent of respondents believe the government should review and verify health-related claims on supplement labels, and nearly as many (73 percent) want claims reviewed and verified before they appear in advertisements (Figure 5).

Although supplement labels are required to include a disclaimer when a "structure/function" claim is made for a product, only 41 percent of supplement users report having noticed such a disclaimer.

Figure 5
Should the Federal Government Verify All Health-Related Claims on Dietary Supplements? (50+ population)



Source: AARP 2001 Survey on Dietary Supplements
Prepared by AARP Public Policy Institute

SUMMARY

The survey found that use of dietary supplements is prevalent among persons age 50 and older. It also indicated that consumers want more safety-related information than is currently found on supplement labels, including possible side effects and drug interactions. Moreover, the survey revealed substantial support among older consumers for federal government premarket review of safety data and health-related claims for supplement products.

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SURVEY QUESTIONS[1]
(N=1,480)

1. How often, if at all, do you take dietary supplements, such as vitamins, minerals, or herbal products?

	%
a. Never	33
b. Less often than once a month	3
c. Once a month	3
d. Weekly	4
e. Daily	52
f. Don't know	5

2. Which, if any, of the following best describes why you don't take dietary supplements, such as vitamins, minerals, or herbal products. Would you say that you don't take them because... (base=451 non-users of supplements)

	%
a. You don't need them	60
b. They don't work	7
c. They're too expensive	18
d. You're concerned about the safety of using them	25
e. You use prescription and over-the-counter drugs instead	27
f. You don't believe in using them	19
g. Your doctor never recommended them	24
h. Don't know	7

3. (If ever use in Q. 1 ask:) Which kind(s) of dietary supplements do you take? (base=1,029 supplement users)

	%
a. Vitamins and minerals, such as multivitamins, vitamin C, or calcium	86
b. Herbs or botanical products, such as garlic, echinacea, or ginkgo biloba	23
c. Other supplements, such as glucosamine, melatonin, bee pollen, and shark cartilage	14
d. Other	2
e. Don't know	10

[1]Due to rounding, response totals for some questions may not equal 100 percent. In other cases, percentage totals may exceed 100 percent since respondents could provide multiple responses.

4. Which, if any, of the following are your reasons for taking dietary supplements? (n=1,029 supplement users)

		%
a.	To treat an existing health condition	31
b.	To prevent a particular disease	27
c.	To promote overall good health	78
d.	To provide nutrients missing in your diet	52
e.	Friends or relatives take them	21
f.	To help lose weight	5
g.	They cost less than prescription and over-the-counter drugs	20
h.	They can't hurt	24
i.	Your doctor or health care provider recommended them	39
j.	Other	1
k.	Don't know	10

Ask Everyone

5. Have you discussed taking dietary supplements with your doctor?

		%
a.	Yes	41
b.	No	53
c.	Don't know	6

6. Which of the following best describes the discussions you had with your doctor?

		%
a.	Your doctor asked you if you were taking anything	21
b.	You checked with your doctor before deciding to take a certain supplement	18
c.	You told your doctor after you started taking a supplement, so he could tell you about possible side effects and drug interactions	15
d.	You discussed taking supplements in general with your doctor	22
e.	You asked your doctor for advice about what you should take for a certain condition	17
f.	Don't know	7

If ever use in Q. 1, continue. Otherwise skip to Q. 10

7. Have you ever used dietary supplements while also taking prescription or over-the-counter medications? (base=1,029 supplement users)

		%
a.	Yes	49
b.	No	41
c.	Don't know	9

8. What kinds of dietary supplements, if any, should not be taken when you take prescription medications? (Verbatim responses)
(base=1,029 supplement users)

   The vast majority of respondents said they didn't know or couldn't think of anything specific. A handful of people said they read labels (12); ask their doctor or pharmacist or don't take anything over-the-counter without discussing it with their doctors (33); or that it depends on the particular medication but did not specify (8). The supplements/drugs mentioned by the very few people who knew there might be interactions include St. John's wort (5), ginko biloba (4), ginseng (1), echinacea (1), and aspirin (6). Vitamins and minerals mentioned include iron (4), vitamin C (3), vitamin E (2), calcium (2), zinc (1), and vitamin K (1).

   Responses were not provided for the questions that had an "other: specify" category.

9. If you took a dietary supplement and thought you had a side effect or adverse reaction to it, what would you do?
(base=1,029 supplement users)

		%
a.	Stop using the supplement	78
b.	Contact a physician or other health care professional	64
c.	Contact the poison control center	15
d.	Go to a hospital	29
e.	Contact the manufacturer	17
f.	Contact the store where you bought the supplement	18
g.	Contact the Food and Drug Administration	13
h.	Other	1
i.	Don't know	12

Ask Everyone

10. Do you think the federal government should review the safety data for a dietary supplement product and approve the product before it is sold to consumers?

		%
a.	Yes	77
b.	No	11
c.	Don't know	13

11. Here are some of the types of information that people have told us they'd like to see on supplement labels. Which information do you think would be very important to appear on supplement labels?

		%
a.	The amount you should take	81
b.	The maximum amount that is safe to take	81
c.	What the supplement does, for example, helps you sleep, boosts immune system	76
d.	Information on possible side effects or adverse reactions	82
e.	Information on interactions with prescription and over-the-counter medicines	80
f.	Expiration date, that is, the date after which a supplement is no longer effective	82
g.	Information on whom to contact in case of an adverse reaction	76
h.	Other	1
i.	Don't know	11

12. The label on a dietary supplement containing calcium might say, "calcium reduces the risk of osteoporosis," or, "calcium helps build strong bones." Do these two statements mean the same thing or are they different?

		%
a.	Mean the same thing	38
b.	Different	43
c.	Don't know	19

13. Should the federal government review and verify health-related claims and approve them before they can be included

		Yes (%)	No (%)	Don't know (%)
a.	On dietary supplement labels	76	9	15
b.	In advertisements for dietary supplements	73	12	15

If ever use in Q. 1, continue. Otherwise, skip to Q. 16.

14. Certain claims made on the labels of dietary supplement products are accompanied by the following disclaimer: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease." Have you ever seen this statement on a supplement label?
(base=1,029 supplement users)

		%
b.	Yes	41
c.	No	39
d.	Don't know	20

15. Did seeing the statement increase your interest, decrease your interest, or make no impact on your decision to try the dietary supplement products?
(base=1,029 supplement users)

		%
a.	Increase	12
b.	Decrease	28
c.	No impact	57
d.	Don't know	3

Ask Everyone

16. To which, if any, of the following organizations do you belong?

		%
a.	AFL-CIO	4
b.	AARP	43
c.	AAA	26
d.	Don't know/no response	44