Statement of John M. Taylor
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Introduction

Good morning, Mr. Chairman, Members of the Committee. I am John M. Taylor, Director, Office of Enforcement, Office of Regulatory Affairs (ORA), Food and Drug Administration (FDA or the Agency). I am pleased to be here this morning to participate in this discussion of "health fraud," specifically as it relates to dietary supplements. I will describe FDA's role, some successes, and challenges in combating this threat to public health - particularly as it is targeted to our senior citizens and other vulnerable populations.

Health Fraud

What is health fraud? Health fraud is the deceptive promotion, advertising, distribution, or sale of articles represented as being effective to diagnose, prevent, cure, treat, or mitigate an illness or condition, or provide a beneficial effect on health but has not been scientifically proven safe and effective for such purposes. You do not have to look far to find a health product that is potentially fraudulent, or a consumer who is totally unsuspecting. Promotions for fraudulent products appear daily in newspaper and magazine ads and television "infomercials." They accompany products sold in stores and through mail-order catalogs. They also are passed along by word of mouth.

The Internet is another method by which fraudulent products can be promoted. The use of the Internet by our nation's citizens, from school age children to seniors, has opened up vast new opportunities for the exchange of information and for enhancing commerce in all types of consumer products. The Internet is rapidly transforming the way we live, work, and shop in all sectors of the economy. In the health sector, tele-medicine allows people in remote areas to access the expertise of doctors in the nation's finest academic health centers. The Internet also permits an increasing number of individuals to obtain a plethora of medical information that often helps them to understand health issues and treatment options. As beneficial as this technology can be, it also creates a new marketplace for activity that is already illegal, such as the sale of unapproved new drugs, prescription drugs (Rx) dispensed without a prescription, and products marketed with fraudulent claims about health benefits. Furthermore, because the Internet is a worldwide communications system, U.S. citizens are now susceptible to fraud from sources outside the U.S. as well as domestically.

Consumers respond to these promotions, spending billions of dollars a year on fraudulent health products, according to Stephen Barrett, M.D., head of Quackwatch Inc., a non-profit corporation that combats health fraud. Hoping to find a cure for their illness, improve their well-being, or even their appearance, consumers often fall victim to products and devices that do nothing more than cheat them out of their money, steer them away from useful proven treatments, and possibly do more harm than good.

In general, these promotions are not specifically targeted to one population - such as senior citizens - as the goal is to quickly establish a broad customer base and maximize sales before being "found out." Given the types of claims that these products make, however, one could certainly extrapolate that some of these products are intended primarily for senior citizens. While FDA's law enforcement efforts cannot be defined by population and demographics, our education and outreach efforts do certainly strive to reach specific populations, which I will describe later.

FDA's mission is to protect and promote the public health. While we are first and foremost a science-based public health agency, we also are a law enforcement agency. It is in both of these capacities that we strive to meet our mission of protecting consumers against health fraud. Strong law enforcement tools - including a cadre of seasoned law enforcement agents and sufficient statutory authority - coupled with a strong base of medical and scientific expertise to evaluate marketed health products are vital to the Agency's ability to meet its mission of protecting the public health.

Let me first provide a brief background on dietary supplements and drugs and the statutory framework under which they are regulated.

Background

Dietary Supplements

Congress defined the term "dietary supplement" in the Dietary Supplement Health and Education Act (DSHEA) of 1994. A dietary supplement is a product that is ingested, is intended to supplement the diet and, among other requirements, contains a "dietary ingredient." The "dietary ingredients" in these products may include vitamins, minerals, herbs or other botanicals, amino acids, and dietary substances such as enzymes. Dietary ingredients also can be metabolites, constituents, extracts, concentrates, or combinations of the preceding types of ingredients. Dietary supplements may be found in many forms, such as tablets, capsules, liquids, or bars. Information on their label must not represent the product as a conventional food or a sole item of a meal or diet. Instead, DSHEA placed dietary supplements in a special category under the general umbrella of "foods" and requires that every supplement be labeled as a dietary supplement.

The dietary supplement industry has grown exponentially since the enactment of DSHEA. Today's multi-billion dollar dietary supplement industry is now one of the world's fastest growing industries. In the past, dietary supplements were mainly sold to adults in health food stores. These products can now be purchased in supermarkets, retail stores, and even through the Internet, making them available to a much wider range of consumers of all ages.

The Washington Post reported last month on just herbal supplements. The Post stated that "Americans alone bought $4.5 billion worth of such popular preparations as

St. John's wort, echinacea and many others. . . ." Further, according to a graph in the article, the $4.5 billion spent by Americans last year is up from around $3 billion in 1996. The full range of dietary supplement product sales is reported to have reached $17.1 billion in 2000.(1) Between 1994 and 2000, consumer spending on dietary supplements nearly doubled, and sales continue to grow at better than ten percent a year.(2)

In a survey conducted last year by PREVENTION Magazine ("Survey of Consumer Use of Dietary Supplements," Rodale Press, 733 Third Ave., New York, New York 10017-2000) over 158 million consumers use dietary supplements. Further, the survey found that consumers use dietary supplements to help them achieve their self-care goals and as a means of ensuring good health. They also use them for "medicinal" purposes such as treating and preventing various illnesses, colds, flu, increasing mental sharpness, and alleviating depression. The consumer's desire for self-care and the widespread use of dietary supplements raises a number of issues, including the possibility of:

- harmful interactions between dietary supplements and prescription or over-the-counter (OTC) pharmaceutical products;

- substituting unproven treatments for proven medical treatments;
- taking products that have no health benefit;
- adverse effects; and,
- the focus of this hearing - health fraud.

When Congress passed DSHEA, it created a unique regulatory framework for dietary supplements. Its purpose was to strike the right balance between providing consumers access to dietary supplements and truthful information about them, while preserving regulatory authority for FDA to take action against supplements that present safety problems or that are labeled or promoted in a false or misleading fashion.

As you know, the regulation of dietary supplements is, for the most part, a post-marketing program, and they are regulated by FDA's Center for Food Safety and Applied Nutrition (CFSAN). Since Congress considered dietary ingredients marketed prior to the passage of DSHEA to be safe, dietary supplements containing these ingredients are permitted to be freely marketed, just like regular foods (e.g., fresh fruits and vegetables, processed foods and beverages, and seafood). Should safety problems arise after marketing, the adulteration provisions of the statute come into play. Under DSHEA, a dietary supplement is adulterated if, among other reasons, it or one of its ingredients presents "a significant or unreasonable risk of illness or injury" when used as directed on the label or under normal conditions of use (if there are no directions). The burden of proof is on FDA to show that a product or ingredient presents such a risk.

Drugs

The mission of FDA's Center for Drug Evaluation and Research (CDER) is to assure that safe and effective drugs are available to the American public. They work to accomplish this mission through a commitment that lasts for the lifetime of the product - from the early stages of drug review and approval to monitoring the products once they reach the marketplace.

Consumers usually think of drugs as the medicines they take to treat illnesses, but most Americans use CDER-regulated drug products every day to maintain health. Drugs include more than just medicines. For example, fluoride toothpastes, antiperspirants, dandruff shampoos, and sunscreens are all considered "drugs," within the meaning of the Federal Food, Drug, and Cosmetic (FD&C) Act.

Most drugs CDER regulates are manufactured by a chemical process. They can include:

1. Prescription drugs: medicines that must be administered under a doctor's supervision or require a doctor's authorization for purchase;
2. OTC drugs: medicines that are available to consumers without a doctor's prescription. Consumers can successfully diagnose many common ailments and treat them with readily available OTC products; and,
3. Generic drugs: medicines that are chemical clones of a drug sold under a brand name. There are generic versions of prescription drugs and OTC drugs.

Ailing Americans and their health care providers have at their disposal more than 10,000 FDA-approved drugs that have met the world's most rigorous reviews for safety and effectiveness. Drug companies seeking to sell a "new drug" in the U.S. must first test it, and prove that it is safe and effective for its intended use before it can be approved for marketing. CDER adheres strictly to its high requirements for drug approval, which are recognized as the world's gold standard.

Among its other activities, CDER is taking steps to make drugs safer for older adults, who consume a proportionately larger share of the nation's medicines. Adults over 65 buy 30 percent of all prescription drugs and 40 percent of all OTC drugs. Almost every drug that comes through FDA for approval has been examined for effects in the elderly.

In 1997, FDA finalized a rule that requires drug companies to include a separate "Geriatric Use" section in their drugs' labeling. Drug companies do not have to perform additional studies, but must include available information in a specific format and location on the label.

Of all the problems older adults face in taking medications, drug interactions are probably the most dangerous. When two or more drugs are mixed in the body, they may interact with each other and produce uncomfortable or even dangerous side-effects. This is especially a problem for older adults because they are much more likely to take more than one drug. Two-thirds of adults over the age of 65 use one or more drugs each day, and one-quarter of them take three drugs each day.

There also is evidence that older adults tend to be more sensitive to drugs than younger adults, because of their generally slower metabolism and organ functions. As people age, they lose muscle tissue and gain fat tissue, and their digestive systems, liver, and kidney functions diminish. All this affects how a drug will be absorbed into the bloodstream, react in the organs, and how quickly it will be eliminated. Not all combinations are bad. However, unless supervised by a doctor, taking a mixture of products can be dangerous.

FDA as a Law Enforcement Agency

As I mentioned, while we are a science-based public health agency, FDA also is a law enforcement agency. FDA is charged with protecting American consumers by enforcing the FD&C Act, its implementing regulations, and several related public health laws (e.g., the Public Health Service [PHS] Act).

FDA shares Federal oversight of dietary supplements with the Federal Trade Commission (FTC). FDA regulates safety, product manufacturing and product labeling. FTC has primary responsibility for regulating the advertising of these products.

When a problem arises with a product regulated by FDA, the Agency can take a number of actions to protect the public health. For dietary supplements, as with other products, initially, the Agency works with the marketer of the product to correct the problem voluntarily. If that fails, the Agency also can ask the marketer to recall a product voluntarily; seek, through the courts, seizure of violative products and/or injunction against firms or individuals who market violative products, and detain or refuse entry of products presented for import at U.S. ports. When warranted, criminal penalties - including prison sentences - are sought through the courts, as well as against those who violate the law.

As an agency that protects the health of all Americans, FDA must keep in touch with consumers and firms dealing with regulated products all over the U.S. FDA's ORA is the lead office for all field activities for the Agency, and represents about one-third of FDA's personnel. Stationed in more than 150 District Offices, Resident Posts and Laboratories from coast to coast and in Puerto Rico, ORA's highly trained staff provides the eyes, ears, and long arm of the Agency that assures the implementation of FDA's public health standards.

Some of the major activities of ORA include:

1. Consumer Safety Officers and inspectors conduct about 16,000 domestic and foreign inspections per year to assure that regulated products destined for the U.S. market are in compliance with the law and meet the Agency's standards;
2. Scientists in ORA's 13 laboratories analyze about 30,000 products each year to determine their adherence to the law and the Agency's standards; and,
3. Public affairs specialists reach out to consumer groups, health-care professionals, and State health authorities to explain FDA policies and encourage compliance with the law and FDA standards.

My office, the Office of Enforcement (OE), is one of four offices in ORA. OE is the lead office for setting regulatory and compliance policy for the Agency, and coordinates and directs FDA's overall compliance efforts.

In addition, the Office of Criminal Investigations (OCI), within ORA, is FDA's criminal investigative arm. OCI is a traditional criminal investigative agency staffed by experienced Special Agents drawn from a wide variety of agencies throughout Federal law enforcement. Their job is to identify and investigate suspected criminal violations of the FD&C Act, PHS Act, and related Title 18, United States Code violations.

ORA works in close cooperation and coordination with all of FDA's Centers (the Centers) in enforcing the law. With regard to health fraud specific to dietary supplements, CFSAN has the lead and is responsible for the oversight of dietary supplements. CDER also has a role to play, as many of the most successful cases the Agency has brought concerned products purporting to be dietary supplements that were actually drugs within the meaning of the FD&C Act and failed to meet the regulatory requirements that drugs must meet prior to their introduction into interstate commerce.

How A Case Is Made

Health fraud, as with any other violation of the FD&C Act or PHS Act, can be brought to the Agency's attention in a variety of ways. For example, FDA's investigators often identify the violations while conducting inspections. FDA may also identify a violation or a suspected fraudulent product through routine market-place surveys, searches on the Internet; adverse event reports; complaints from consumers; competitors or public interest groups; informants; or through referrals from the FTC or other Federal, State, or local government authorities.

As with all of FDA's activities, priorities are established based on benefit/risk to public health. The Agency's regulation of health fraud products is based on a priority system that depends on whether a fraudulent product poses a direct or indirect risk to public health. The susceptibility of the population is an element that is considered when determining risk. For example, terminal cancer patients would be considered highly susceptible, as many have exhausted conventional or standard of care treatments, and are desperate to try anything that may promise a cure.

Products that present a direct health hazard to the user are the Agency's highest priority. Such products include those, which have a reasonable potential for causing direct serious adverse effects, or there is documentation of injury or death. Examples of such products include tiratricol, dinitrophenol, and gammabutyrolactone (GBL). When such products are encountered, the Agency will use all available civil and administrative remedies to assure that the product is quickly removed from the market. Publicity is used to warn consumers and health professionals about such products. The decision to open a criminal investigation is based primarily on the public health threat level, indications of criminal intent, and the scope of the violation, as well as the potential impact of an effective prosecution.

Products that are not themselves hazardous can still present an indirect health hazard in that the consumer may delay or forego proven medical treatment and the use of proven drug therapies. Examples include unproven products promoted for the treatment of cancer, Alzheimer's disease, arthritis, heart disease, and high blood pressure.

In addition to these direct and indirect health risks, priorities are also established with respect to risks posed by such products in undermining the integrity of the new drug application (NDA) and OTC Drug Review processes. The NDA and OTC Drug Review procedures provide consumers with assurance that Rx and OTC Drugs are both safe and effective. To avoid undermining these procedures, it is essential for FDA to maintain vigorous surveillance, provide prompt industry guidance and outreach, and take enforcement action regarding fraudulent products. Coupled with a credible threat of enforcement, the Agency's actions assure that manufacturers are properly motivated to bear the costs of developing "new drugs" in conformance with the NDA provisions and that the playing field is fair and equitable for those who do.

Examples of FDA Enforcement Actions

Despite the complexities involved in building and bringing an enforcement action, the Agency, working with the Department of Justice's (DOJ) Office of Consumer Litigation, has been successful in bringing cases against fraudulent products in all categories of FDA-related products. Let me discuss a few examples.

Christian Brothers

Last November, Christian Brothers Contracting Corporation and its President, Jason Vale, signed a consent decree of permanent injunction in which they agreed to stop manufacturing, processing, and distributing the firm's amygdalin products, also referred to as Laetrile, Vitamin B-17 or apricot kernels. This case was developed in conjunction with the FTC and DOJ. Despite repeated warnings by FDA, the products continued to be promoted through numerous websites for the cure, treatment, and prevention of cancer.

Amygdalin is a glucoside found in the kernel or seeds of many fruits and is frequently referred to as "Laetrile" or "Vitamin B-17." While some of the proponents have recommended it for the treatment and control of cancer, FDA has never approved these claims. There are no published clinical studies that demonstrate that laetrile is safe and effective and cancer patients who take it sometimes forgo conventional therapies to their detriment.

World Without Cancer Inc., The Health World International, Health Genesis Corporation, and David E. Arjona, an officer of the three corporations

Last summer, FDA and DOJ, with the assistance of FTC, sought a temporary restraining order, preliminary injunction, and permanent injunction against the marketing of unapproved new drugs by three corporations and one individual. The products, laetrile, in injectable and tablet form, and apricot seeds, were promoted as cancer treatments through their Internet websites. Despite FDA warnings to these companies in 1998, they continued to promote their products as remedies for cancer. In January 2001, District Court Judge Shelby Highsmith entered a Consent Decree of Permanent Injunction in this case with regard to defendants World Without Cancer, Health Genesis Corporation, and David E. Arjona. The preliminary injunction and Consent Decree of Permanent Injunction required the defendants to cease using the websites to promote the sale or offer for sale their laetrile products.

United States v. Syntrax Innovations, Inc., et al.

This case involved a drug called Triax Metabolic Accelerator, marketed by Syntrax as a dietary supplement for the treatment of obesity and to promote weight loss. FDA scientists determined that Triax posed a serious health hazard to those who consumed the product. The product contained tiratricol, a potent thyroid hormone, that FDA medical review identified as a hazardous compound that could cause heart attacks and strokes. FDA alleged that Triax could not be a dietary supplement because it was promoted to treat a disease (obesity) and because it did not contain any of the dietary ingredients identified in the definition set forth in DSHEA.

This case began as a seizure by DOJ, but the government amended the complaint to request injunctive relief. Syntrax originally contested the case, but later conceded that Triax is a drug. On February 14, 2001, a District Court Judge entered an order of injunction to prevent the distribution of Triax by Syntrax Innovations.

Hit Products

This case demonstrates the extremes to which promoters of fraudulent products will go to create a market for their products. These products were marketed towards a younger consumer base. Hit Products, Inc., and Organic Diversions, Inc., were marketing products made from a mixture of herbs that promised users effects comparable to illegal street drugs. FDA categorized these products as "street drug alternatives" and charged that they were misbranded and unapproved new drugs in violation of the FD&C Act. Therefore, the government seized the violative products.

The court found FDA's position on street drug alternatives "highly persuasive" and criticized the defendant's characterization of the products as dietary supplements as a "veiled attempt to circumvent" the FD&C Act. The court "decline[d] to carve out a statutory loophole for drug manufacturers attempting to profit from the illegal drug epidemic by masquerading potentially dangerous substances as dietary supplements." This case was the Agency's first suit following issuance of a guidance document in

April 2000 informing the public that any product promoted as an alternative to illegal street drugs would be regarded by FDA as a misbranded and unapproved new drug.

Nature's Nutrition Formula One

FDA determined that this pre-DSHEA product, which was marketed between 1992 and 1994 as an all natural "nutritional supplement" that contained plant ingredients, was actually made with two pharmaceutical-grade chemicals, ephedrine hydrochloride and caffeine anhydrous. FDA received more than 100 reports of injuries and adverse reactions related to the product, ranging from serious and life-threatening conditions, such as irregular heartbeat, heart attack, stroke, seizures, hepatitis and psychosis, to relatively minor and temporary conditions such as dizziness, headache and gastrointestinal distress. At least one death was associated with the use of this product.

This case was developed by the alerts provided from the adverse event reports, ORA's field staff, and the work of OCI together with DOJ, FDA learned that the Chemins Company, Inc., which manufactured the product, went to great lengths to hide its actions from the Agency and concealed the actual ingredients of Formula One. As a result, the government initiated a criminal prosecution against the company and its president, James Cameron.

On July 7, 2000, a Federal judge sentenced James Cameron to 21 months in jail and fined him and this corporation $4.7 million. In his plea agreement, Mr. Cameron admitted that he and his company labeled Formula One as "all natural" but secretly spiked the product with synthetic ephedrine hydrochloride and caffeine anhydrous. He also admitted that the product's labeling failed to disclose the use of the chemicals on the list of ingredients, and that he and his employees had misled FDA investigators and hindered inspections of Chemins. The sentence marked the culmination of a three-year investigation. Mr. Cameron, whose company continues to make dietary supplements, began serving his sentence in September 2000.

In addition, FDA and DOJ have pursued seizures of a number of unapproved drugs that have been promoted on the Internet as dietary supplements, including GBL and 1,4 butanediol. FDA also has sought product recalls and achieved the voluntary destruction of 18 products containing these substances.

Other Activities To Combat Health Fraud

The Agency has a number of ongoing activities directed at combating health fraud. Many of these activities are the result of a strategy plan begun by FDA in 1992, to improve their processes for targeting and coordinating regulatory activities between ORA, field, headquarters units, the Centers, Office of General Council and other Federal/State/local regulatory and law enforcement agencies. This strategy also focused on improving the Agency's efforts to educate the public about the importance of making wise choices concerning their health care.

Health Fraud Working Group

In 1992, FDA began sponsoring a National Health Fraud Working Group. The Working Group is currently comprised of representatives from the Association of Food and Drug Officials, State Attorneys General, FTC, Health Canada, and FDA representatives from the center and field offices. This group meets on a regular basis to facilitate the coordination of regulatory activities, information exchange, and leveraging of each member agency.

The Working Group is currently considering ways in which their activities and outcomes can be improved upon. Preliminary discussions include the benefits that may be achieved by expanding the membership to include representatives from non-governmental organizations that combat health fraud.

AIDS Health Fraud Task Force Network

FDA sponsors a network of AIDS Health Fraud Task Forces throughout the U.S. The Task Forces, which are currently located in 19 States, maintain a proactive approach to combat fraudulent products and treatments affecting people with HIV/AIDS and their families. The network strives to promote awareness and prevent fraud through education that empowers individuals to make informed decisions about their health care. The Task Forces have developed hotlines, workshops, conferences, and advocacy sharing as an alert mechanism to new fraudulent product promotion. The media has been utilized to broaden awareness in the diverse communities that are served by the Task Force. Members of the Task Force Network include persons living with HIV/AIDS, community-based organizations, treatment advocates, health care practitioners, educators, Federal and State government officials, and local health departments.

"Operation Cure.All"

In 1997, FTC, FDA, Health Canada, and various State Attorneys General organized and implemented an ongoing and comprehensive law enforcement and consumer education campaign against the fraudulent marketing of supplements and other health products on the Internet. The agencies have moved to stop Internet scams for supplements and other products that purport to cure cancer, HIV/AIDS and countless other life-threatening diseases.

FDA has made Internet surveillance an enforcement priority; the Agency's partnership with FTC, and others, in "Operation Cure.All," further demonstrates FDA's commitment to monitoring violative conduct on the Internet. Collaboration on all "Operation Cure.All" activities maximizes FDA's effectiveness in communicating to the Internet community that the various regulatory and law enforcement agencies are working together to combat health fraud. All activities are coordinated in order to ensure consistent results in areas where FTC, FDA, the States and Health Canada have jurisdiction.

Since its inception, "Operation Cure.All" has resulted in 48 cyber-letters directed at sites selling colloidal silver products with egregious disease claims as well as several enforcement activities directed against the marketing of fraudulent products.

In addition, the Agency has engaged in several consumer education efforts with FTC including a "Facts for Consumers" brochure that is focused on fraudulent claims and spotting quackery and health fraud. Today, we are announcing with FTC the publication of a recently revised brochure, "Miracle Health Claims: Add A Dose of Skepticism."

Internet Activities

Over the past several years, FDA has sharpened its focus on the issue of Internet promotion and sale of drugs as online activity has expanded. In 1996 and again in 1999 FDA held public meetings to discuss and examine the issue of promoting, prescribing and dispensing drugs online.

In July 1999, FDA adopted, and has since been implementing, an Internet Drug Sales Action Plan to expand and improve its activities in addressing the unlawful sale of drugs over the Internet. The illegally marketed drugs targeted by the plan include a variety of fraudulent products, including counterfeit drugs, drugs marketed with fraudulent health-related claims, and unapproved new drugs masquerading as dietary supplements. The plan is based on internal deliberations, meetings with Federal and State regulatory and law enforcement bodies, as well as organizations representing consumers, health care practitioners, and the pharmaceutical and pharmacy industries. The elements of the plan include, among others:

- Public Outreach: FDA Talk Papers, articles in the *FDA Consumer* magazine, and information on FDA's website to help educate consumers about safely purchasing drugs online.

- Professional Outreach and Partnering: Periodic meetings with State and Federal regulatory and law enforcement bodies, consumers, health care practitioners and industry to share information and strategize about how to address the challenges the Internet presents.

- Coordinating Activities with other State and Federal Agencies: Established cooperative working relationships with DOJ, the Drug Enforcement Administration, the Federal Bureau of Investigation, FTC, U.S. Postal Service, U.S. Customs Service, and other appropriate Federal and State law enforcement agencies.

- International Cooperation: Because FDA and other Federal agencies possess limited investigatory jurisdiction over sellers in foreign countries, we must work with foreign governments to bring action against such individuals.

Take Time To Care Campaign (TTTC)

One of the Agency's most successful campaigns has been FDA's Office of Women's Health (OWH), "Take Time To Care" Campaign. While the campaign is not specifically targeted to preventing or educating against health fraud, the success of the program in educating women about using medicines wisely certainly should lessen the chances that the women educated will fall prey to the marketers of fraudulent products.

Started in 1997 as a pilot, expanded in 1998, and rolled out nation-wide in 1999, the intent of the campaign was to educate women and their families about safe medicine use. The key element of the campaign is the "My Medicines" brochure. Colorful and compact, it includes tips for taking medicines correctly as well as a personal record card for tracking medicine use. Like the entire TTTC campaign, the brochure is designed primarily for women, who use more medication than any other group and often manage medications for their whole family. The purse-sized brochure promotes four key messages: Read the Label, Avoid Problems, Ask Questions, and Keep a Record.

In order to maximize FDA's OWH impact, the OWH initiated partnerships with local health and social service organizations, pharmacies, senior centers, religious congregations, universities, women's groups, and workplaces. In 1999, the National Association of Chain Drug Stores (NACDS) joined OWH as an official co-sponsor. As a result of their work and innovative collaboration, the campaign in partnership with 80 national organizations and NACDS distributed over 6 million "My Medicines" brochures in a single month. This now successful national campaign was the subject of a presidential proclamation and received a public endorsement from the American Medical Association.

Conclusion

While FDA tries to be vigilant against health fraud, many fraudulent products escape regulatory scrutiny, maintaining their hold in the marketplace for some time to lure increasing numbers into their web of deceit. For every such marketer that we put out of business, another or more appear. As long as there are vulnerable populations to prey upon, there will continue to be those unsavory and unscrupulous characters who do so.

Mr. Chairman, combating health fraud is a challenge, especially in light of the advent of the Internet, and one to which the Agency is committed to addressing. Our partnerships with our law enforcement, public health, State, local and international colleagues expand FDA's reach and impact. Good enforcement strategies and enforcement actions, vigilant oversight of the marketplace, and sufficient legal authority to remove these products from the market is not enough. Successfully combating health fraud must include educating our citizens to recognize fraud when they see it, and warning them of the potential dangers that some of these products pose. Only through these steps can we help the public make fully informed decisions about their health care purchases, and thereby reduce the number of people who may fall prey to these fraudulent products.

We have a strong education program, and we applaud hearings such as this, which bring this issue to national prominence. Thank you for the opportunity to participate in this hearing. We look forward to working with you as we grapple with health fraud as a nation. I would be happy to answer any questions you might have.

[1] "U.S. Dietary Supplements Market Size Expressed as Dollar Sales by Top Six Product Categories for 1994 to 1998 and Forecast for 1999 and 2000," National Business Journal, 2000, Dialog file No. 93, San Francisco: The Dialog Corporation, 2000.

[2] Nutrition Business Journal, San Diego, 1998.