COUNTY OF LOS ANGELES
Public Health

JONATHAN E. FIELDING, M.D., M.P.H.
Director and Health Officer

JONATHAN E. FREEDMAN
Chief Deputy Director

313 North Figueroa Street, Room 806
Los Angeles, California 90012
TEL (213) 240-8117 • FAX (213) 975-1273

www.publichealth.lacounty.gov

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May 14, 2012

TO: Each Supervisor

FROM: Jonathan E. Fielding, M.D., M.P.H. JEFielding m
Director and Health Officer

SUBJECT: **CONSUMER PROTECTION**

This is in response to the December 20, 2011 Board motion directing 1) the Director of the Department of Public Health (DPH) and Health Officer to report back on efforts to inform the public of safe and effective alternative methods to achieve and maintain a healthier weight; 2) Chief Executive Officer (CEO) and Director of Public Health to develop a plan to identify medical products and services that are being marketed in a dangerously misleading manner; 3) County Counsel to report back on legal options to ensure truthful advertising of aggressive obesity treatment procedures in unincorporated areas in a manner that would comply with the First Amendment of the United States Constitution and other laws; and 4) CEO to pursue legislation that would strengthen the regulation and oversight of surgical centers and clinics performing aggressive and invasive obesity treatment cosmetic procedures to ensure quality of care standards are in place at these clinics and checked by the appropriate credentialing agencies.

This report serves as the response to items one and two. County Counsel will provide a response to item three under a separate cover. The CEO responded to item four on February 29, 2012.

I. Safe and Effective Alternative Methods to Achieve and Maintain a Healthier Weight

Through multiple programs, DPH supports a wide range of community-focused efforts around healthful eating and active living that supports the adoption of healthy lifestyles. While direct services related to achieving and maintaining healthy body weight (i.e. weight loss programs and counseling services) have not historically been a focus of DPH, the adoption of healthy habits is recognized as the key component of successful weight management. DPH activites range from small group nutrition education and related public education campaigns, to policy work in schools, worksites, cities, and county programs.

In the Fall of 2009, the Board instructed DPH to address nine strategic priorities that would establish or expand activities to promote nutrition, the following six were focused on the local

level: 1) strengthen nutrition literacy; 2) improve neighborhood food environments; 3) prevent early onset childhood obesity; 4) promote breastfeeding and baby-friendly hospitals; 5) increase affordability of fresh fruit and vegetables among food stamp recipients; 6) improve the food environment in County facilities and programs. These strategies are aimed at making healthy living easier for all County residents. DPH efforts to promote better nutrition and physical activity for County residents have largely mirrored these strategies.

DPH Activities and Strategies Related to Achieving and Maintaining a Healthy Weight

The DPH Nutrition Program participates in the Network for a Healthy California, a statewide campaign focused on increasing consumption of fruits and vegetables and other healthy foods, increasing levels of physical activity, and decreasing food insecurity among low-income individuals and families. The program's efforts include targeted education campaigns for Latino and African-American communities, worksites, retail establishments, schools, and community-based organizations. The Nutrition Program supports the Los Angeles Collaborative for Healthy Active Children, a coalition comprised of 100 member organizations focused on reducing obesity in low-income children and families throughout the County. The Nutrition Program also promotes healthy foods through the "Ask the Dietitian program," which is focused on connecting County residents with nutrition experts at farmers' markets.

A variety of programming is provided by the DPH Community Health Services Division (CHS). Health Educators in Service Planning Areas (SPA) 1 developed "Fed Up," an educational program focused on obesity and nutrition targeted at youth; the program was derived from a larger effort in SPA 3, Healthy Eating Active Communities (HEAC). Efforts in SPAs 1 and 2 have included work in schools and the development of a partnership between Public Health Nurses and school-based parenting classes for English as a Second Language learners. Staff in SPA 1 also championed school-based summer feeding programs that provide nutritious foods to children during the summer months when school is not in session. Staff in SPAs 3 and 4 have promoted healthy beverages through "ReThink Your Drink", an education campaign focused on reducing the consumption of sugar-sweetened beverages. Health Educators in various SPAs, most notably SPA 6, have worked with local restaurant owners to educate them on healthful foods and assist them with improving the nutritional content of menu offerings. Staff in SPAs 7 and 8 have focused their work in the area of food policy, supporting school-based efforts around policies that encourage healthy behaviors.

The DPH Maternal, Child, and Adolescent Health (MCAH) Program is working with child care providers to improve the foods offered in their facilities and promote physical activity. Having already developed nutrition guidelines and a toolkit for improving early childhood nutrition and physical activity practices, MCAH is currently conducting research to identify improvements needed in the foods served and physical activity offered in childcare facilities. One hundred and twenty childcare centers in SPA 6 are participating; study results are expected to be available later this year. MCAH has also worked to compile web-based resources on good nutrition, including a collection of resources for obesity prevention. In addition, MCAH has focused on the promotion of healthy weight for women of reproductive age, as a woman's pre-conception

body weight is strongly related to outcomes for both mother and baby. MCAH maintains a Healthy Weight Collaborative, the focus of which has been developing recommendations for healthcare providers who work with women of reproductive age.

DPH Children's Medical Services (CMS) has worked closely with the California Office of Multicultural Health to create educational materials for parents and children. CMS partnered with the Nutrition, Dental, and Health Education subcommittees of the California Child Health and Disability Prevention Program to develop guidelines for feeding children of all age groups, from birth to adulthood. CMS has also created a variety of nutrition-related presentations and print materials, and made them available online.

The DPH Office of Women's Health (OWH) slogan – Be Active, Eat Smart, Quit Smoking, Get Checked – reflects its commitment to nutrition and physical activity promotion. Through their referral and appointment hotline, OWH will conduct a healthy heart risk assessment for any woman, regardless of age or financial status. This assessment includes an evaluation of disease risk, education on a variety of topics as determined during the call, and fact sheets (available in six languages) based on a summary of identified risk factors. OWH also produces a monthly Healthy Note, emphasizing various educational topics including nutrition. Weight management is also covered, in the context of heart health, and includes basic education on reducing caloric intake, increasing consumption of healthy foods, and being physically active.

In 2007, DPH established the Policies for Livable, Active Communities and Environments (PLACE) Program which works with other County departments, city planners, and transportation officials to promote environments conducive to health. Work begun by PLACE has since been expanded by a Centers for Disease Control and Prevention (CDC) funded project, Renew Environments for Nutrition, Exercise, and Wellness (RENEW) LA County, the goal of which is to improve nutrition and increase physical activity in cities, schools, and communities. RENEW has supported public education activities, referred to as "Choose Health LA," which reflects the program's effort to empower communities to create environments that support healthy choices. A major focus of "Choose Health LA" is educating communities about evidence-based strategies to discourage consumption of sugar-sweetened beverages, which have been shown to be a major contributor to the obesity epidemic.

RENEW has helped transform the food environment in Los Angeles County through community market conversions, by guiding store owners to provide nutritious options and implementing marketing strategies to encourage the sale of nutritious foods. In schools, RENEW is working with local districts to improve the quality of school meals while concurrently providing physical education training for teachers, in order to build capacity for schools to meet California requirements for physical education minutes. At the city level, RENEW is working to increase accessibility of healthy foods and beverages, targeting cities in which childhood obesity rates are above the county average. 10 cities have adopted policies that include nutrition guidelines for procurement of foods and beverages offered at city institutions and facilities; later this year, RENEW will be launching a public education effort in these communities to raise awareness of the adverse health consequences of consuming large amounts of high-sugar, low-nutrition drinks.

RENEW has also provided guidance on revisions to the County vending machine policy, and has collaborated with other County departments to expand the healthy food and beverage options provided through worksite cafeterias. RENEW staff has convened a task force focused on expanding safe, open spaces for recreation through joint-use agreements and expanded bicycle networks. RENEW supported the Departments of Public Works and Regional Planning in the update of the County's Bicycle Master Plan.

Although the grant funding for RENEW is ending in July, 2012, DPH was awarded a one-year Community Transformation Grant (CTG) by the CDC in October 2011. This grant will be extended an additional four years, through September 2016, contingent upon available federal funding through the Prevention and Public Health Fund of the Affordable Care Act. Under the banner of Choose Health LA, the CTG funding will provide resources to build upon the successes of RENEW in providing nutrition education and improving access to healthy foods and beverages in community, school, and workplace settings.

II. Plan to Identify Medical Products and Services that Are Being Marketed in a Dangerously Misleading Manner

Residents of Los Angeles County can be harmed when they are exposed to misleading and inaccurate product or service promotions related to health. DPH is developing an approach to identify health-related products and services being marketed in a dangerously misleading manner. This response describes the potential harms associated with confusing or disingenuous health promotion; summarizes current regulatory pathways and enforcement gaps; outlines the role of DPH in consumer protection and advocacy; and proposes a plan to identify and address deceptive health product/service promotions to Los Angeles County residents.

Potential Harms Associated with Marketing of Medical Products

Many consumers are not equipped to assess the truthfulness and completeness of promotional claims, for the benefits and harms of health-related products and services. This is significant as many products and services have associated risks and potential harms. These can be:

> Direct – The service or product can cause direct harms by containing harmful substances, triggering interactions with other drugs, or causing direct injury, such as from anesthesia or a clinical procedure; or
>
> Indirect – The service or product can intentionally lead to follow-up services that can be harmful or, in misleading the consumer, can delay necessary treatments or beneficial care.

An example is a clinical preventive service that is widely promoted, but not recommended by national authorities: screening asymptomatic older adults for stroke-risk using carotid ultrasound. While not likely to be harmful by itself, detection of potential narrowing of the carotid artery leads to additional testing and, for some, surgical intervention or stenting. These procedures

usually carry death rates of 3 percent or greater which exceeds the potential benefit of reduction in the risk of strokes among individuals who are otherwise asymptomatic. Invariably, medical and surgical procedures have some level of risk which is inadequately disclosed in marketing materials. For reference, attached is the list of clinical preventive services that are *not* recommended by the U S Preventive Services Task Force for adults.

Promotions that omit the potential harms and risks of medical products and services mislead consumers about the full scope of possible impacts. The U S Food & Drug Administration (FDA) requires that approved drugs and devices provide a level of disclosure of risks on all labeling, packaging, and promotion.

Also challenging is that many alternative and complementary medicines, including dietary supplements, have uncertain benefits and harms. In general, supplements that have biological effects are likely to have interactions with other medications, and those with no biological effects offer no documented benefits.

Current Regulatory Framework

The regulatory environment of health-related products and services is complex. In general, Federal agencies possess regulatory authority over pharmaceuticals, medical products, and devices. Specifically, the Food and Drug Administration (FDA) regulates drugs and medical devices, including laboratory tests, and requires the manufacturers to show safety and effectiveness and allows promotion only within the FDA-approved indication. FDA requires that promotions with respect to drugs must also provide "fair balance" so that the harms are presented as well as the benefits. FDA enforcement activities with respect to devices are also based on "fair balance" principles, although the federal statutory scheme is not as precise nor as robust on this point. The FDA can pursue enforcement through a variety of means, including removal of the product from the marketplace Medicaid costs.

Dietary supplements are also regulated by the FDA, but unlike drugs and devices, for supplements, the burden is on the FDA to prove harm. In certain instances, damages can be imposed to the extent that fraudulent promotion has caused federal governmental expenditures, most frequently as Medicare and The U S Federal Trade Commission (FTC) regulates promotion of consumer products including lower risk Class I and Class II medical devices. To stop fraudulent advertising practices, the FTC pursues remedies including legal enforcement through federal district courts. Medical practice is regulated by state medical practice laws.

The State of California generally holds regulatory powers over medical practice including health professions and health facility licensure, and disciplinary actions, regulatory compliance. Health facilities are regulated by the California Department of Public Health, and physicians (including oversight of physician-owned outpatient facilities) is governed by the California Medical Board. The California Business and Professions Code Sections 17200 and 17500 also have requirements related to false and misleading business practices. Business and Professions Code actions can be brought by public attorneys.

At the local level, the County Department of Consumer Affairs (DCA) investigates consumer claims from residents and compiles evidence for cases on behalf of local and State prosecuting entities, including the Los Angeles City Attorney, the Los Angeles County District Attorney, and the California Attorney General.

In 1999, the County established the Health Authority Law Enforcement Taskforce (HALT), which is a multi-agency, multi-jurisdictional team of enforcement professionals from the Department of Health Services, the California State Department of Health Services Medi-Cal Fraud Division, Los Angeles County Sheriff's Department, Los Angeles Police Department, County Counsel, the Los Angeles County District Attorney's Office (District Attorney), and the Los Angeles City Attorney's Office. HALT was created to combat and deter criminal activity including: selling prescription medicine without a license or prescription; practicing dentistry or medicine without a license; illegally operating blood labs, forced alcohol aversion therapy clinics; and conducting illegal State Medi-Cal billing practices.

In many instances, regulatory and enforcement agencies face serious resource constraints which limit their ability to adequately monitor or act on improper promotions occurring in Los Angeles County.

Proposed Future Actions by DPH

Historically, DPH has not had a systematic approach to identifying misleading promotion of health-related products and services. DPH has had no resources dedicated to this broad area. Moving forward, DPH could strengthen its efforts in consumer protection in the following ways:

Develop Prioritization Criteria

DPH will establish systematic criteria to identify and elevate detrimental promotional activity for review and possible referral to an appropriate regulatory agency for investigation. Criteria could include: the importance of the problem; how commonly the product or service is used; the magnitude of the harms; the prominence of the promotion; and the ability to affect change. Attached are two examples of potential harmful products that are promoted to the public.

Interagency Consumer Protection Partnerships

With additional resources, DPH could establish new and strengthen existing partnerships with local, State, and federal agencies and organizations that possess the appropriate regulatory authorities for action. Based on discussions with several potential partners, key partners could include the FDA, the FTC, State Attorney General's office, the California Medical Board, DCA, the Los Angeles City Attorney, and the District Attorney. In order to capitalize on these partnerships, early collaboration efforts will focus on the development of appropriate mechanisms for sharing information to identify misleading promotions and to initiate action.

Interagency partnerships could yield the following:

- Notifying and informing promoters of specific concerns and request changes in their marketing practices;
- Educating physicians on consumer protection through DPH's monthly newsletter, *Rx for Prevention*;
- Working with County Counsel and DCA;
- Informing the public through DPH-sponsored community-based activities, including distributing consumer materials from consumer protection partners listed above;
- Issuing Public Health Notices on the DPH website related to misleading promotions, and provide related materials to help consumers make healthful decisions (e.g., fact sheets, tips for healthy living);
- Distributing reports on consumer issues based on data analysis from surveillance findings; and
- Directing letters to regulatory agencies requesting investigations of misleading promotions, as employed in the case of the 1-800-GET-THIN promotion for Lap Bands®.

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Attachments

c: Chief Executive Officer
Acting County Counsel
Executive Officer, Board of Supervisors
District Attorney
Director of Health Services
Director of Consumer Affairs

Non-Recommended Clinical Prevention Services
US Preventive Services Task Force

The services listed below have received a "D" rating by the US Preventive Services Task Force (USPSTF). These services are *not* recommended for the general asymptomatic population and therefore should not be covered as preventive services within a medical benefit plan. However, these services may play an important role in the diagnostic work-up of symptomatic patients and in the treatment or management of existing conditions and should be covered as indicated for all populations under the health plan's treatment benefit.

Services	Explanation
Abdominal Aortic Aneurysm in women, *Screening*	The USPSTF recommends against routine screening for AAA in women.
Aspirin Therapy for the Primary Prevention of Cardiovascular Disease for specific populations, *Counseling*	The USPSTF recommends against the use of aspirin for stroke prevention in women younger than 55 years and for myocardial infarction prevention in men younger than 45 years.
Aspirin Therapy for the Primary Prevention of Colorectal Cancer, *Counseling*	The USPSTF recommends against the routine use of aspirin and nonsteroidal anti-inflammatory drugs (NSAIDs) to prevent colorectal cancer in individuals at average risk for colorectal cancer.
Asymptomatic Bacteriuria in men and nonpregnant women, *Screening*	The USPSTF recommends against the routine screening of men and nonpregnant women for asymptomatic bacteriuria.
Bacterial Vaginosis among low-risk pregnant women, *Screening*	The USPSTF recommends against screening for bacterial vaginosis in asymptomatic pregnant women at low risk for preterm delivery.
Bladder Cancer, *Screening*	The USPSTF recommends against routine screening for bladder cancer in adults.
Breast Cancer, *Preventive medication for low or average-risk women*	The USPSTF recommends against routine use of tamoxifen or raloxifene for primary prevention of breast cancer for women at low or average risk for breast cancer.
Breast Cancer, *Screening*	The USPSTF recommends against teaching breast self-examination (BSE).
Carotid Artery Stenosis, *Screening*	The U.S. Preventive Services Task Force (USPSTF) recommends against screening for asymptomatic carotid artery stenosis (CAS) in the general adult population.

Cervical Cancer in women over 65 years, *Screening*	The USPSTF recommends against routinely screening women older than age 65 for cervical cancer if they have had adequate recent screening with normal Pap smears and are not otherwise at high risk.
Cervical Cancer in women with hysterctomy, *Screening*	The USPSTF recommends against routine Pap smear screening in women who have had a total hysterectomy for benign disease.
Colorectal Cancer in adults over age 85, *Screening*	The USPSTF recommends against screening for colorectal cancer in adults older than age 85 years.
COPD Screening using Spirometry, *Screening*	The USPSTF recommends against screening adults for chronic obstructive pulmonary disease (COPD) using spirometry.
Coronary Heart Disease, *Screening*	The USPSTF recommends against screening with resting electrocardiography (ECG), exercise treadmill test (ETT), or electron-beam computerized tomography (EBCT) scanning for coronary calcium for either the presence of severe coronary artery stenosis (CAS) or the prediction of coronary heart disease (CHD) in adults at low risk for CHD events.
Gonorrhea, *Screening*	The USPSTF recommends against routine screening for gonorrhea infection in men and women who are at low risk for infection.
Genetic Risk Assessment and BRCA Mutation Testing for Breast and Ovarian Cancer Susceptibility	USPSTF recommends against routine referral for genetic counseling or routine breast cancer susceptibility gene (BRCA) testing for women whose family history is not associated with an increased risk for deleterious mutations in breast cancer susceptibility gene 1 (BRCA1) or breast cancer susceptibility gene 2 (BRCA2).
Hemochromatosis, *Screening*	The USPSTF recommends against routine genetic screening for hereditary hemochromatosis in the asymptomatic general population.
Hepatitis B Virus Infection, *Screening*	The USPSTF recommends against routinely screening the general asymptomatic population for chronic hepatitis B virus infection.
Hepatitis C, *Screening*	The USPSTF recommends against routine screening for hepatitis C virus (HCV) infection in asymptomatic adults who are not at increased risk (general population) for infection.

Herpes (Genital), *Screening*	The USPSTF recommends against routine serological screening for HSV in asymptomatic adolescents and adults or in asymptomatic pregnant women at any time during pregnancy to prevent neonatal HSV infection.
Hormone Therapy in postmenopausal women, Preventive Medication	The USPSTF recommends against the routine use of combined estrogen and progestin for the prevention of chronic conditions in postmenopausal women. The USPSTF recommends against the routine use of unopposed estrogen for the prevention of chronic conditions in postmenopausal women who have had a hysterectomy.
Idiopathic Scoliosis, *Screening*	The USPSTF recommends against the routine screening of asymptomatic adolescents for idiopathic scoliosis.
Lead Levels in average-risk children, *Screening*	The USPSTF recommends against routine screening for elevated blood lead levels in asymptomatic children aged 1 to 5 years who are at average risk.
Ovarian Cancer, *Screening*	The USPSTF recommends against routine screening for ovarian cancer.
Pancreatic Cancer, *Screening*	The USPSTF recommends against routine screening for pancreatic cancer in asymptomatic adults using abdominal palpation, ultrasonography, or serologic markers.
Peripheral Arterial Disease, *Screening*	The USPSTF recommends against routine screening for peripheral arterial disease (PAD).
Prostate Cancer in men over age 75, *Screening*	The USPSTF recommends against screening for prostate cancer in men age 75 years or older.
Syphilis Infection in average-risk adults, *Screening*	The USPSTF recommends against routine screening of asymptomatic persons who are not at increased risk for syphilis infection.
Testicular Cancer, *Screening*	The USPSTF recommends against routine screening for testicular cancer in asymptomatic adolescent and adult males. Vitamin Supplementation, Preventive Medication The USPSTF recommends against the use of beta-carotene supplements, either alone or in combination, for the prevention of cancer or cardiovascular disease.