# N.Y. City Gives Cash Incentives for Health Care

### BY JOHN R. BELL Associate Editor

NEW YORK — A new program in New York City that pays low-income families for obtaining preventive medical care and for maintaining health insurance is garnering its share of praise and skepticism among physicians who practice there.

Under the pilot program, Opportunity NYC, which began in September, families will receive \$20 per parent or guardian per

month via wire transfer for maintaining public health insurance or \$50 for maintaining private health insurance, and the same amount for maintaining insurance for all children in the family. Funding is being provided through corporations as well as from Mayor Michael Bloomberg, who conceived the idea.

The program also pays enrolled parents when their children attend school regularly, get a library card, or do well on tests. Other payments reward preventive dental care and continued parental employment.

Although the payment amount is relatively low, the hope is that it will serve as an incentive for families who already have public health insurance to recertify their eligibility, Linda I. Gibbs, New York's deputy mayor for health and human services, said in an interview. For the small number of participants who don't qualify for public health insurance because they are employed, the payments will help offset the higher cost of private insurance.

To encourage preventive care, participants are paid \$200 for each annual preventive visit to any physician in their plan. Physicians are required to provide ageappropriate preventive care. "We know that many families, even with public health insurance, are not going to those annual preventive visits." And even when they do go, "doctors are not always providing all of the [preventive care] that the child or the adult should be getting during that visit."

Childhood vaccinations would fall under required preventive care services, she said. When the preventive visit indicates a follow-up visit or treatment is necessary for any family member, the family receives a \$100 payment for that visit as well.

Dr. Mark Krotowski, who practices family medicine in the Canarsie area of Brooklyn, near the target neighborhood of Brownsville, was sanguine about the program's potential. "With the cash incentives, it'll certainly encourage the parents to bring in the kids," said Dr. Krotowski, who is chairman of family medicine at the borough's Brookdale Hospital.

Dr. Krotowski noted that the incentives may help primary care physicians combat childhood obesity, which he says is "probably the biggest medical challenge in New York City. If we can get the kids early, we can refer them to specialists who deal with obesity and try to take care of them."

The state of New York already has a fairly efficient system for providing medical care to its low-income residents via the HMO Medicaid or HMO Child Health Plus programs, Dr. Krotowski added.

Dr. Linda Prine, a family physician at Sidney Hillman Health Center in New York, said that she is underwhelmed by the program's ability to have any real impact. This program is a drop in the bucket and does not begin to address the problem of lack of affordable health care for the uninsured. People at this level of poverty cannot afford the monthly premiums to buy health insurance, even with a rebate of \$20-\$50," said Dr. Prine, chair of the Public Health Commission of the New York State Academy of Family Physicians.

The cost of the program, which so far is operating solely from private funding, makes its long-term viability uncertain, according to Dr. Andrew D. Racine, vice president of the American Academy of Pediatrics chapter that covers the Bronx, Manhattan, and Staten Island.

"Obviously, the American Academy of Pediatrics is delighted with any sort of rethinking of how we can improve the health status of children," but the opportunity costs have to be addressed, Dr. Racine said in an interview.

"If you decide you're going to spend X amount of money to induce people to maintain health insurance, there are a lot of ways to skin that cat." he said. Direct cash for medicine is one option; another is to extend Medicaid enrollment to automatically last for 2 years instead of 1.

We know that there are things that we could be doing to maintain health insurance in children that we're not already doing," said Dr. Racine, who also is director of general pediatrics at the Children's Continued on following page

# **LOVAZA**<sup>™</sup>

## (omega-3-acid ethyl esters) Capsules

Brief Summary of Prescribing Information CLINICAL STUDIES High Triglycerides: Add-on to HMG-CoA reductase inhibitor therapy The effects of Lovaza 4 g per day as add-on therapy to treatment with simvastatin were evaluated in a randomized, placebo-controlled, double-blind, parallel-group study of 254 adult patients (122 on Lovaza and 132 on placebo) with persistent high triglycerides: (200 – 439 mg/dL) despite simvastatin therapy (Table 1). Patients were treated with open-label simvastatin 40 mg per day for 8 weeks prior to randomization to control their LDL-C to no greater than 10% above NCEP ATP III goal and remained on this dose throughout the study. Following the 8 weeks of open-label weeks with simvastatin co-therapy. The median baseline triglyceride and LDL-C levels in these patients were 268 mg/dL and 98 mg/dL, respectively. Median baseline non-HDL-C and HDL-C levels were 138 mg/dL and 45 mg/dL, nges in the major lipoprotein lipid parameters for the Lovaza plus simvastatin and the placebo plus sim-orouos are shown in Table 1.

Table 1: Response to the Addition of LOVAZA 4 g per day to On-going Simvastatin 40 mg per day Therapy in Patients with High Triglycerides (200 to 499 mg/dL)

Parameter	LOVA	LOVAZA + Simvastatin N=122			bo + S N=1	imvastatin 32	Difference	P-Value
	BL	EOT	Median % Change	BL	EOT	Median % Change		
Non-HDL-C	137	123	-9.0	141	134	-2.2	-6.8	< 0.0001
TG	268	182	-29.5	271	260	-6.3	-23.2	< 0.0001
TC	184	172	-4.8	184	178	-1.7	-3.1	< 0.05
VLDL-C	52	37	-27.5	52	49	-7.2	-20.3	< 0.05
Аро-В	86	80	-4.2	87	85	-1.9	-2.3	< 0.05
HDL-C	46	48	+3.4	43	44	-1.2	+4.6	< 0.05
LDL-C	91	88	+0.7	88	85	-2.8	+3.5	=0.05
BL = Baseline (mg/dL); EOT = End of Treatment (mg/dL); Median % Change = Median Percent Change from Baseline; Difference =								

Lovaza 4 g per day significantly reduced on-HDL-C, TG, TC, VLDL-C, and Apo-B levels and increased HDL-C and LDL-C from baseline relative to placebo.

LDL-C from baseline relative to placebo. Very High Triglycerides: Monotherapy The effects of Lovaza 4 g per day were assessed in two randomized, placebo-controlled, double-blind, parallel-group studies of 84 adult patients (42 on Lovaza, 42 on placebo) with very high triglyceride levels (Table 2). Patients whose baseline triglyceride levels were between 500 and 2000 mg/dL were enrolled in these two studies of 6 and 16 weeks duration. The median triglyceride and LDL-C levels in these patients were 792 mg/dL and 100 mg/dL, respectively. Median HDL-C level was 23.0 mg/dL. The changes in the major lipoprotein lipid parameters for the Lovaza and placebo groups are shown in Table 2.

Table 2: Median Baseline and Percent Change From Baseline in Lipid Parameters in Patients with Very High TG Levels (≥500 mg/dL)

			• ,				
Parameter	LOV N=	AZA 42	Plac N=	Difference			
	BL	% Change	BL	% Change			
G	816	-44.9	788	+6.7	-51.6		
lon-HDL-C	271	-13.8	292	-3.6	-10.2		
C	296	-9.7	314	-1.7	-8.0		
/LDL-C	175	-41.7	175	-0.9	-40.8		
IDL-C	22	+9.1	24	0.0	+9.1		
.DL-C	89	+44.5	108	-4.8	+49.3		
= Baseline (mg/dL); % Chg = Median Percent Change from Baseline; Difference = Lovaza Median % change - Placebo Mediai							

% change Lovaza 4 g per day reduced median TG, VLDL-C, and non-HDL-C levels and increased median HDL-C from baselin relative to placebo. Lovaza treatment to reduce very high TG levels may result in elevelstons in LDL-C and non-HDL C in some individuals. Patients should be monitored to ensure that the LDL-C level does not increase excessively. The effect of Lovaza on the risk of pancreatilis in patients with very high TG levels has not been evaluated. The effect of Lovaza on cardiovascular mortality and morbidity in patients with elevated TG levels has not been deter mined.

NDICATIONS AND USAGE Very High Triglycerides Lovaza is indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with very high (≥500 mg/dL) triglyceride levels.

Jsage Considerations: n indivduals with hyper Usage Considerations: In indivduals with hypertriglyceridemia (HTG), excess body weight and excess alcohol intake may be important con-tributing factors and should be addressed before initiating any drug therapy. Physical exercise can be an important ancillary measure. Diseases contributory to hypertipidemia, (such as hypothyroidism or diabetes mellitus) should be looked for and adequately treated. Estrogen therapy, thiazide diuretics, and beta blockers are sometimes associ-ated with massive rises in plasma TG levels. In such cases, discontinuation of the specific etiologic agent, if med-ically indicated, may obviate the need for specific drug therapy for HTG. The use of lipid-regulating agents should be considered only when reasonable attempts have been made to obtain satisfactory results with non-drug methods. If the decision is made to use lipid-regulating agents, the patient should be advised that use of lipid-regulating agents does not reduce the importance of adhering to diet (See PRECAU-TIONS).

CONTRAINDICATIONS Lovaza is contraindicated in patients who exhibit hypersensitivity to any component of this medica PRECAUTIONS

General: Initial Therapy: Laboratory studies should be performed to ascertain that the patient's TG levels are consistently abnormal before instituting Lovaza therapy. Every attempt should be made to control serum TG levels with appropri-ate diet, exercise, weight loss in overweight patients, and control of any medical problems (such as diabetes melli-tus and hypothyroidism) that may be contributing to the patient's TG abnormalities. Medications known to exacer-bate HTG (such as beta blockers, thiazides, and estrogens) should be discontinued or changed, if possible, before considering TG-lowering drug therapy.

Continued Therapy: Laboratory studies should be performed periodically to measure the patient's TG levels during Lovaza therapy. Lovaza therapy should be withdrawn in patients who do not have an adequate response after 2 months of treatment.

monns or ureautern. Information for Patients: Lovaza should be used with caution in patients with known sensitivity or allergy to fish. Patients should be advised that use of lipid-regulating agents does not reduce the importance of adhering to diet.

In some patients, increases in alanine aminotransferase (ALT) levels without a concurrent increase in aspartate aminotransferase (AST) levels were observed. Alanine aminotransferase levels should be monitored periodically dur-ing Lovaza therapy.

In some patients, Lovaza increased low-density lipoprotein cholesterol (LDL-C) levels. As with any lipid-regulating product, LDL-C levels should be monitored periodically during Lovaza therapy.

Drug Interactions: Anticagulants: Some studies with omega-3-acids demonstrated prolongation of bleeding time. The prolongation of bleeding time reported in these studies has not exceeded normal limits and did not produce clinically significant bleeding episodes. Clinical studies have not been done to thoroughly examine the effect of Lovaza and concomitant anticoagulants. Patients receiving treatment with both Lovaza and anticoagulants should be monitored

HMG-CoA reductase inhibitors: In a 14-day study of 24 healthy adult subjects, daily co-administration of simvas tatin 80 mg with Lovaza 4 g did not affect the extent (AUC) or rate (C<sub>max</sub>) of exposure to simvastatin or the majo active metaholitic heta-hydroxy simvastatin at teach vertee.

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Cytochrome P450-Dependent Monooxygenase Activities: Omega-3-fatty acid containing products have been shown to increase hepatic concentrations of cytochrome P450 and activities of certain P450 enzymes in rats. The potential of Lovaza to induce P450 activities in humans has not been studied.

Carcinogenesis, Mutagenesis, Impairment of Fertility: In a rat carcinogenicity study with oral gavage doses of 100, 600, 2000 mg/kg/day by oral gavage, males were treat-ed with omega-3-acid ethyl esters for 101 weeks and females for 89 weeks without an increased incidence of tumors (up to 5 times human systemic exposures following an oral dose of 4 g/day based on a body surface area comparison). Standard lifetime carcinogenicity bioassays were not conducted in mice. Omega-3-acid ethyl esters were not mutagenic or clas openic with or without metabolic activation in the bacterial includes the state of the new new process of the state of

Induce inicionaucus assay. In a rat fertility study with oral gavage doses of 100, 600, 2000 mg/kg/day, males were treated for 10 weeks prior to mating and females were treated for 2 weeks prior to and throughout mating, gestation and lactation. No adverse effect on fertility was observed at 2000 mg/kg/day (5 times human systemic exposure following an oral dose of 4 g/day based on a body surface area comparison).

Pregnancy Category C: There are no adequate and well-controlled studies in pregnant women. It is unknown whether Lovaza can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Lovaza should be used during pregnancy only if the potential benefit ustrifies the potential risk to the fetus. Omega-3-acid ethyl esters have been shown to have an embryocidal effect in pregnant rats when given in doses resulting in exposures 7 times the recommended human dose of 4 g/day based on a body surface area comparison. In female rats given oral gavage doses of 100, 600, 2000 mg/kg/day beginning two weeks prior to mating and con-tinuing through gestation and lactation, no adverse effects were observed in the high dose group (5 times human systemic exposure following an oral dose of 4 g/day based on body surface area comparison).

In pregnant rats given oral gavage doses of 1000, 3000, 6000 mg/kg/day from gestation day 6 through 15, no adverse effects were observed (14 times human systemic exposure following an oral dose of 4 g/day based on a body surface area comparison).

uouy surrace area comparison). In pregnant rats given oral gavage doses of 100, 600, 2000 mg/kg/day from gestation day 14 through lactation day 21, no adverse effects were seen at 2000 mg/kg/day (5 times the human systemic exposure following an oral dose of 4 g/day based on a body surface area comparison). However, decreased live births (20% reduction) and decreased survival to postnatal day 4 (40% reduction) were observed in a dose-ranging study using higher doses of 3000 mg/kg/day (7 times the human systemic exposure following an oral dose of 4 g/day based on a body surface area comparison). of 3000

comparison). In pregnant rabbits given oral gavage doses of 375, 750, 1500 mg/kg/day for gestation day 7 through 19, no find-ings were observed in the fetuses in groups given 375 mg/kg/day (2 times human systemic exposure following an oral dose of 4 g/day based on a body surface area comparison). However, at higher doses, evidence of maternal tox-icitly was observed (4 times human systemic exposure following an oral dose of 4 g/day based on a body surface area comparison).

after comparison, Nursing Mothers: It is not known whether omega-3-acid ethyl esters are excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Lovaza is administered to a woman who is breastleeding.

Pediatric Use: Safety and effectiveness in pediatric patients under 18 years of age have not been established.

Geriatric Use: A limited number of patients over 65 years of age were enrolled in the clinical studies. Safety and efficacy findings in subjects over 60 years of age did not appear to differ from those of subjects less than 60 years of age.

ADVERSE REACTIONS Treatment-emergent adverse events reported in at least 1% of patients treated with Lovaza 4 g per day or placebo during 8 randomized, placebo-controlled, double-blind, parallel-group studies for HTG are listed in Table 3. Adverse events led to discontinuation of treatment in 3.5% of patients treated with Lovaza and 2.6% of patients treated with

nized Placebo-Controlled Double-Blind Parallel-G

High TG Levels (≥ 500 mg/dL) that Used LOVAZA 4 g per Day							
BODY SYSTEM	LOV (N =	AZA 226)	Placebo* (N = 228)				
Adverse Event	n	%	n	%			
Subjects with at least 1 adverse event	80	35.4	63	27.6			
Body as a whole Back pain Flu syndrome Infection Pain	5 8 10 4	2.2 3.5 4.4 1.8	3 3 5 3	1.3 1.3 2.2 1.3			
Cardiovascular Angina pectoris	3	1.3	2	0.9			
Digestive Dyspepsia Eructation	7 11	3.1 4.9	6 5	2.6 2.2			
Skin Rash	4	1.8	1	0.4			
Special senses Taste perversion	6	2.7	0	0.0			

 6
 2.7
 0
 0.0

 Adverse events were coded using COSTART, version 5.0. Subjects were counted only once for each body system and for each preferred term.
 \*Placebo was corn oil for all studies.

Additional adverse events reported by 1 or more patients from 22 clinical studies for HTG are listed below: BODY AS A WHOLE: Enlarged abdomen, asthenia, body odor, chest pain, chills, suicide, fever, generalized edema, fun-gal infection, malaise, neck pain, neoplasm, rheumatoid arthritis, and sudden death. CARDIOVASCULAR SYSTEM: Arrhythmia, bypass surgery, cardiac arrest, hyperlipemia, hypertension, migraine, myocardial infarct, myocardial ischemia, occlusion, perpineral vascular disorder, syncope, and tachycardia. DIGESTWE SYSTEM: Anorexia, constipation, dry mouth, dysphagia, colitis, fecal incontinence, gastritis, gastrointestinal disorder, increased appetite, intestinal obstruction, melena, pancreatitis, tensemus, and vomiting. HEMATOLOGIC-LYMPHATIC SYSTEM: Lymphadenopathy. INFECTIONS AND INTERTIONAL DISOPDERS: Edema, hyperglycemia, increased ALT, and increased AST. MUSCULOSKELETAL SYSTEM: Arthraigia, arthritis, myalgia, pathological fracture, and tendon disorder. NERVOUS SYSTEM: Martin lervous system neoplasia, depression, dizziness, emotional lability, facial paralysis, insomia, vasodilatation, and vertigo. RESPIRATORY SYSTEM: Asthma, bronchitis, increased cough, dyspnea, epistaxis, laryngitis, pharyngitis, pneumonia, minitis, and sinusitis.

Non-Boll and Sinustits. SKIN: Alopecia, eczema, pruritus, and sweating. SPECIAL SENSES: Cataract. UROGENITAL SYSTEM: Cervix disorder, endometrial carcinoma, epididymitis, and impotence.

DRUG ABUSE AND DEPENDENCE Lovaza does not have any known drug abuse or withdrawal effects.

Rx only

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OVERDOSAGE In the event of an overdose, the patient should be treated symptomatically, and general supportive care measures instituted, as required.

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### (omega-3-acid ethyl esters) Capsules

Continued from previous page

Hospital at Montefiore, in New York. That said, Dr. Racine expressed full support for the aspects of the program that encourage preventive care. "The principle of actually using cash incentives to get people to do things is great. It's sort of the opposite of taxing. You tax things that you don't want people to do, and this is sort of an inverse tax," he said.

Currently, 5,100 families are being recruited via the schools' free-lunch program in six city neighborhoods in which the poverty rates exceed 40%. Candidates must have children in the fourth, seventh, or ninth grades and must be documented legal residents or U.S. citizens.

An equal number of families (2,550) will be randomly assigned to a study group and to a control group in order to study the

# **Families Might Override** Organ **Donation Plans**

ORLANDO — Patient wishes for organ donation were overridden by family members in about 20% of cases, creating "missed opportunities" for organ procurement, according to research conducted at a level I trauma center in Charlotte, N.C.

Dr. A. Britton Christmas and colleagues at the F.H. Sammy Ross Jr. Center at the Carolinas Medical Center reviewed 3 months of organ donation referrals at their center. They estimated that about 17 potential transplant recipients did not receive organs because a patient's previous donation intentions were overridden by family members. The research was presented in a poster at the annual congress of the Society of Critical Care Medicine.

The researchers examined charts to determine the appropriateness for donation, familial consent or denial for donation, and the number of organs transplanted from each donor. They compared their records with data from the state department of motor vehicles (DMV) related to organ donation designations.

The researchers analyzed information on 84 individuals who had information on file with the DMV and whose families had been approached by hospital staff for organ donation over the 3-month period. According to DMV records, 25 individuals were listed as organ donors, and 59 had not designated organ donation.

For the 25 individuals who had designated themselves as organ donors, 20 consents for donation were obtained from family members. Of the remaining 59 individuals, 22 consents for organ donation were obtained.

Although the organ recovery rate was higher among those who had already specified a desire to be donors (80% vs. 37%), some families chose to override a previous designation of organ donation. With an average of 3.4 organs transplanted from each eligible donor, the researchers estimated that the five individuals whose consent was withdrawn by the families resulted in 17 potential organ recipients who would not receive organs.

—Mary Ellen Schneider

program's efficacy, Ms. Gibbs explained. Because many low-income families do not have bank accounts, the mayor's office recruited four banks and four credit unions to provide free checking accounts for program participants.

Opportunity NYC, which grew out of Mayor Bloomberg's antipoverty Center for Economic Opportunity, is not the first conditional cash transfer program. The government of Mexico offered the first such program to its citizens in 1997, and nearly one-fourth of the population is enrolled, according to a recent New York Times report. Approximately 20 countries now have such programs in place.



Dr. Mark Krotowski, who practices in the Canarsie area of Brooklyn, near the target neighborhood of Brownsville, was sanguine about the program's potential.

Now for the treatment of moderate to severe primary RLS



MIRAPEX is well tolerated and has no predicted P450 interactions

Convenience: MIRAPEX Starter Kit offers simple single-step titration 75% of patients on the 0.25 mg dose responded to therapy\*

IMPORTANT SAFETY INFORMATION ABOUT MIRAPEX: Patients have reported falling asleep without perceived warning signs during activities of daily living, including operation of a motor vehicle. Hallucinations and postural (orthostatic) hypotension may occur. The most commonly reported adverse events in RLS clinical trials for MIRAPEX vs placebo were nausea (16% vs 5%), headache (16% vs 15%), fatigue (9% vs 7%), and somnolence (6% vs 3%).

Patients and caregivers should be informed that impulse control disorders/compulsive behaviors may occur while taking medicines, including pramipexole, to treat Parkinson's disease and RLS. Please see accompanying Brief Summary of Prescribing Information.

\*Results of a 12-week, placebo-controlled, randomized, double-blind, fixed-dose-treatment trial to assess the efficacy and safety of MIRAPEX vs placebo in the treatment of moderate to severe primary RLS.

Responders defined as patients with symptoms rated as "much improved" or "very much improved," as measured on the CGI-I. Reference: 1. Data on file, Boehringer Ingelheim Pharmaceuticals, Inc.



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