

Health Letter

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New York City's Answer to the Diabetes Epidemic Screen, Trace, Track, and Act: More Public Health, Fewer Pharmaceuticals

Whom do physicians judge to be "the greatest doctor of all time?" While Hippocrates, Maimonides, Sigmund Freud, and Jonas Salk are probably better known among the public at large, hospital doctors voted for John Snow when the question was posed in a survey conducted in 2003. Who was John Snow, and why does his work still resonate more than 125 years after his death?

Known as the "father of epidemiology," John Snow is best known for his research and forceful action when cholera raged through the Soho neighborhood of London in 1854. Although the prevailing belief was that cholera was airborne, Snow had a different opinion. He hypothesized that cholera was a disease of the alimentary canal in which the causative agent entered through the mouth. As the cases of cholera mounted, Snow reasoned that the transmission of cholera was due to contaminated water. And because the outbreak was relatively localized, he surmised that the source of the contamination was most likely a pump or a well. Snow located the homes of the victims and mapped the spread of the disease. He discovered that, while there were five water pumps in the neighborhood, most of the victims lived closer to the pump on Broad Street. Further research confirmed the culprit: some of the victims who lived

at a distance from the pump had nonetheless preferred the Broad St. water and relied on that source. Snow presented his findings to skeptical

community leaders, and they agreed to remove the handle of the Broad Street pump. The epidemic abated, confirm-
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November is National Diabetes Month, and Health Letter has taken the opportunity to update its readers on new modalities of prevention and treatment at a moment of increased urgency in dealing with the rising prevalence of this disease. We hope you will appreciate a fresh set of topics on a frequently-discussed theme.

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ing Snow's hypotheses. Although there were still disbelievers concerning both the cause of the cholera epidemic and its eventual resolution, a subsequent investigation of the well found that an underground sewer pipe was leaking raw sewage into the drinking water, thus contaminating the water supply.

These methods of mapping, tracing, tracking and acting that John Snow so effectively employed are now part of the epidemiological armamentarium that cities, states, and nations deploy. Although routinely used in the control of communicable diseases, the efficacy of these tools is not limited to that category of disease. Indeed, John Snow himself felt that it was the prevention of epidemics, whatever their origins, that was worthy of investigation, "for diseases influence the life, the death, and the numbers of the human race, more than all others."

The lessons of John Snow shed light on how to address epidemic health problems in general. And they are increasingly pertinent now that the United States is in the midst of a diabetes epidemic that, in the absence of effective intervention, can only get worse. In this country, the estimated lifetime risk of acquiring diabetes for someone born in 2000 is 32.8 percent for males and 38.5 percent for females. With such odds, it is surprising that so little is being done to intervene more forcefully. Yet, in many ways, type 2 diabetes, which is responsible for approximately 90 to 95 percent of all diabetes, is an ideal model for chronic disease prevention. It affects many people, has an array of risk factors that are amenable to change, and there is significant research showing that control of risk factors can effectively prevent or mitigate the disease and its complications. Moreover, type 2 diabetes has a long asymptomatic phase, in which the disease often goes undetected. Early diagnosis is critical if complications are to be prevented, delayed, or reversed.

While some of the risk factors for the disease do not lend themselves to change (aging, genetic predisposition,

socio-economic status), many others involve lifestyle factors over which the patient exerts a measure of control. These include diet, physical activity, stress, smoking, and obesity. At the same time, the risks of **not** doing anything are considerable. The complications of diabetes include coronary heart disease, stroke, lower limb amputation, impotence, kidney failure, and blindness. Even those who do not have diabetes are affected by it: in taking care of others, in higher taxes and insurance premiums, and in public dollars devoted to the disease. The American Diabetes Association estimated that in 2002 the national cost of diabetes was \$132 billion, and that this would rise to \$192 billion in 2020. These figures include not only direct medical expenditures but also the indirect costs of lost days of work, restricted activity, premature mortality, and permanent disability. The control of diabetes can therefore yield significant individual and collective benefits.

Although the combination of high costs and amenability to prevention and treatment makes diabetes an obvious priority for intervention, many cities and states have been reluctant to take forceful measures against the disease. Early this year, however, New York City launched a program to monitor the blood sugar levels of its diabetic residents. Prompted by the fact that the number of people with diabetes in NYC more than doubled over a decade, the city realized that this condition constituted the city's largest health crisis. In fact, diabetes is the only major disease whose prevalence is rising in the city. Moreover, the city's prior experience in setting up a network of diabetes centers had failed, victims of their medical success and perverse reimbursement policies which favor treatment over prevention. The older hospital-based diabetes centers sought to serve as "boot camps" for diabetics, teaching them to check their blood sugar levels, control their food intake, and exercise with discipline, while being monitored by teams of specialists. Within seven years, however, most of the centers shut down because they failed to make money. In the words of *New York*

Times reporter Ian Urbina, the centers closed because of "the byzantine world of American health care, in which the real profit is made not by controlling chronic diseases like diabetes, but by treating their many complications." Health insurers refused to pay \$150 for a diabetic to see a podiatrist who could prevent foot ailments, but covered amputations, which cost more than \$30,000. Similarly, they did not pay \$75 for a counseling session with a nutritionist, but would pay \$315 for a single session of dialysis for a patient who would ultimately need hundreds of such treatments

It is therefore not surprising that the city has now adopted a different community-based strategy, one more reminiscent of John Snow's. Acknowledging that public health officials had been "asleep at the switch" in controlling chronic disease, Thomas Frieden, the city's health commissioner, announced a major change in policy. The city has espoused aggressive surveillance, assumed a more active stance towards diabetes control, and set the goal of reducing diabetes complications by 20 percent by 2008. New York is therefore taking numerous measures to intervene at different points in the onset and development of the disease, beginning with identifying and tracking those at risk.

While disease surveillance is a tried-and-tested means of controlling disease, the NYC program marks the first time that the U.S. government at any level has begun tracking people with a *chronic* disease. The program mandates laboratories to report the results of blood sugar tests directly to the NYC Department of Health and Mental Hygiene, which in turn uses the data to study the disease and prod doctors and patients when levels run too high. Under the plan, all 120 New York medical testing laboratories with the ability to transmit data electronically are required to report the results of the blood test hemoglobin A1c within 24 hours. This test is a cumulative measure of recent levels of blood sugar and thereby serves as a marker for how well diabetics are controlling their condition. The registry of test results will be linked to identifying

information about the patients and about the physicians who ordered the test. The data include the full name, date of birth, and address of the person tested and the date the test was performed. The city will therefore know the number of diabetics whose condition is out of control, where they are, and who is taking care of them. Collectively, this will give the health department excellent intelligence on the prevalence of the disease, as well as on its distribution by demographic and neighborhood characteristics. Over time, the city will be able to pinpoint the geographic 'hot spots' where disease levels are high and greater care is needed. It will also be able to design educational messages targeting vulnerable populations. Treating physicians will receive quarterly summaries of their patients stratified by the success of the blood sugar control, alerts if levels are particularly high, and reminders of best practice recommendations.

But the epidemiological merits of the surveillance approach have made it a lightning rod for those who see it as overly aggressive, and who fear that, under the banner of health promotion and disease prevention, the Department is collecting personal information and intruding into people's medical care. Fear of the "nanny state" has therefore exposed the city to accusations of having adopted "Big Brother" tactics. Opponents of the current policy see public health going down a slippery slope, eventually dismissing informed consent and eroding private rights by not only monitoring personal behavior but also intervening at the individual level. At least one critic has expressed a concern that the next step would be having "a public health worker showing up at your door and asking, 'Did you remember to exercise, eat right and take your medication today?'" Others worry that the program "assigns to government the responsibility for reducing the rate of certain diseases," which is, of course, one of the fundamental principles and aims of public health. In fact, this responsibility may be considered

particularly appropriate in the case of a serious disease whose mounting costs are largely incurred by society.

The city has not been insensitive to this criticism, and allows patients to opt out of any following-up information or intervention once their laboratory findings have been reported. The program has also adopted safeguards to protect patient privacy and the confidentiality of the tests. In consultation with the American Diabetes Association, the NYC Department of Health and Mental Hygiene has instituted measures to insure that the only people outside the department who see a person's test results are the clinician and the patient. Once the registry is fully functional and the data are in, the city expects to carry out a pilot intervention in the South

With other cities and states waiting to see how New York does before launching their own programs, the stakes are high, both politically and in terms of public health.

Bronx, where the diabetes epidemic is raging out of control, accounting for half of the total patient load in some medical centers.

Because the new registry was launched only nine months ago, its effects are not yet visible. But New York is hoping to replicate with diabetes the success it achieved in implementing directly-observed therapy to control tuberculosis (TB) a decade ago. Then, as now, the strategy of combining strict surveillance of the disease with vigorous efforts to get people into treatment was criticized for running roughshod over people's

rights. But criticism was significantly muted once the disease rates declined, and the New York approach to TB control is now considered a national and even an international model.

But there are differences in the two conditions, one of the major ones being that that TB is contagious and can be *cured*, while diabetes can only be *managed*. Moreover, the intervention in the case of TB is largely focused on medication, while the control of diabetes depends on a variety of medical and lifestyle approaches, most of which require the consent and active participation of the patient. In addition, identifying actual and potential patients, while necessary, is not sufficient to control the epidemic. Those diagnosed or at risk for diabetes must be matched to clinicians who can provide ongoing care. Individuals and communities also require education, a supportive environment, and an array of services to insure adherence to healthful practices.

With surveillance as only its first stage, New York City and its health officials are making a significant commitment to control its diabetes epidemic. Yet, because the Diabetes Prevention and Control Program has an annual budget of only \$950,000 and a staff of three, some have questioned the Department of Health's ability to meet its self-imposed goals. Other cities and states are waiting to see how New York does before launching their own programs. As a result, the stakes are high, both politically and in terms of public health.

The NYC Department of Health and Mental Hygiene is aware that its experiment could influence how the public health community confronts the epidemic. In diabetes, there is no "Broad Street Pump" whose handle can be easily removed, thereby controlling the source of the disease. Yet the very complexity of the task makes the challenge worth pursuing. The city is therefore leveraging its own resources to mobilize others in the campaign. It has partnered with the Veterans Administration to reduce obesity and the elevated level of diabetes among retired members of

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A Broader Context: Diabetes in the United States and in the World

In the United States, much has been written about the rising numbers of diabetics and the staggering health care costs associated with the disease. New cases of type 2 diabetes have doubled among middle-aged Americans in the past three decades. New research suggests that being overweight as an adult is the biggest risk factor for developing diabetes.

In 2002, diabetes was the sixth leading cause of death listed on U.S. death certificates, but experts say that death from diabetes is often misreported, and the actual number of deaths attributable to diabetes is probably much higher. This is because diabetes affects almost every system in the body, and often complicates the condition listed as the cause of death.

Treatment is often quite costly, both at home and in the hospital. An average American family with an adult diabetic can expect to pay up to 10 percent of their income on diabetes health care alone. When further health issues arise, the expenses rise as well. The Illinois Health Care Cost Containment Council found that between 1995 and 2000, there was a 30 percent increase in diabetes-related hospitalizations. The average charge for each hospitalization in the year 2000 was \$17,238 — in that year, there were

231,701 hospitalizations with a diabetes diagnosis. These costs are not only the financial burden of the individual, but also of health care and insurance providers, hospitals, and, ultimately, the state.

Two of the key elements to reducing more serious complications due to the condition are prevention and early detection. “Opportunistic” diabetes screening programs have shown promising results in helping to reach patients. A United States Department of Veterans Affairs study demonstrated a solid measure of success in early detection by screening patients for diabetes who were at the doctor for another reason. Four and a half (4.5) percent of the patients screened in this study without previously recognized diabetes were found to be diabetic; of those, 61 percent required a change in their treatment plan based on this new diagnosis.

Famine to Feast: A World-Wide Disaster Foretold

Although it has long been considered a “wealthy man’s burden” confined mostly to the developed world, the “sugar disease”, as it is often called, is not limited by national boundaries. Already it has begun to spread into the developing world on a massive scale. The World Health Organization estimates that as many as four million deaths a year are related to

the presence of the disorder; that accounts for about nine percent of the global total. Diabetes is now poised to become one of the most widespread, devastating pandemics the world has ever known, despite the fact that it is non-communicable and preventable in 90 to 95 percent of cases. In 20 years, three-fourths of diabetics will live in the developing world. It seems that where development goes, diabetes follows as its silent shadow.

The “famine to feast” countries are in a particularly delicate situation in the context of this disease. When discussing globalization, one often hears about the environmental impact of spreading the attractive yet unsustainable American way of life to other parts of the world with much larger populations. But these discussions often omit the more negative aspects of indiscriminately importing new habits and lifestyles. As developing countries westernize, they abandon many of their healthy traditions and adopt some of the more unhealthful customs of the developed world. In India, for instance, although the vast majority of people still live in rural areas, many are migrating to the cities at a rapid rate. It is there that they find higher-paying jobs demanding long, stressful hours in sedentary settings, such as software programming. People who once labored in fields now sit in front of computer screens and exercise little more than a few keystrokes a day. Although a sedentary lifestyle hinders health enough on its own, when combined with convenient Western-style cooking techniques (involving lots of oil, fat and sugar) it becomes a dangerous and fast-acting recipe for diabetes.

A macroeconomic look at the cost of diabetes highlights the expenses for both individuals and the public. Without effective prevention measures, diabetes and its complications are expected to dominate the health economies of many countries by 2025. ■

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the armed forces, banned trans fats in prepared foods, and supported the William J. Clinton Foundation and the American Heart Association in their campaign to change the food habits of school children.

Only success will validate the current approach. The civil libertarian argument that diabetics should be able to keep their condition private and their health information confidential is not without merit. At the same time, health professionals generally

acknowledge that the rules of privacy are not absolute. The public health argument for tracking and acting is that diabetes has become a clear and present danger, and that, given the current state of knowledge of the disease and its rise, thorough surveillance and forceful action are the morally responsible choices. Ultimately, there will have to be a clear payoff to justify trading off personal privacy: public health trumps private rights only when it is clear that some good will be accomplished. ■

What is Diabetes?

Diabetes is a non-communicable disease in which the body either does not produce adequate amounts of or improperly uses the hormone insulin. Without insulin, glucose is unable to enter and re-fuel the body's cells, which require glucose to function, just as a car requires gasoline to run.

There are two major types of diabetes. Type 1, or insulin-depend-

ent, diabetes is less common. The American Diabetes Association estimates that between five and 10 percent of diabetics have this form of the disease. Even though it is not clear what causes type 1 diabetes, family history seems to be a good predictor. This form is usually diagnosed in patients younger than 20 years old, and it must be treated with close monitoring of blood sugar and

multiple daily injections of insulin.

Somewhere between 90 and 95 percent of diabetics have type 2, or "adult onset", diabetes. Type 2 is a combination of insulin production deficiency and inability to adequately use of insulin. Because the body generally has not stopped producing insulin altogether, type 2 diabetics are often able to control the disease through diet and exercise alone. ■

Bogus Cures for Diabetes on the Internet

A joint effort of the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) has resulted in warning letters to 180 companies in the United States, Mexico and Canada who are marketing diabetes treatments online. They have been warned that unless they correct the fraudulent claims about diabetes treatments on their websites, they will be subject to enforcement action (which can include a seizure of products, civil litigation, and criminal prosecution). By law, manufacturers of such products are not allowed to claim that a product will treat, cure, or prevent disease, though they can say that these supplements can improve the structure or function of the body if the assertion is backed up by research. However, some firms have violated the law by saying that their products could replace standard diabetes treatments like metformin or insulin, which could convince people to replace or reduce their treatment regimens. A list of products named by the FDA and FTC accompanies this article. ■

Food Matrix™ Diabetes Pack™
Sportron's Diabetes FoodMatrix™ Pack; CarboTone
Allbaid
Beta Fast GXR Glucose Balance; Beta Fast GXR Glucose Tolerance
Enhansulin®
Diamel®
Charantea
"Glucose Balance;" "Glucose Support"
PureGels GlucoTrim 24; Diamaxol Blood Sugar Support; Jiang Tang Pian (Diabetes Care)
Wai Ola
Pancreas Tonic 180; Grifon Maitake SX; Diabetan
Glucobetic; Neuro-Betic
RiSoTriene
HPB-84
Trilovin DNS; Trilovin DSAO
Diamaxol™
Triple Complex Diabetonic; Insulate Plus; Vizu-All Plus
FoodMatrix diabetic pack (UltraGard Forte; Omegatone; Calcitone; Carbotone)
Vitamin Research Products Biotin 10mg; Vitamin Research Products Optimum D; and Vitamin Research Products GluControl
Glucose M1; Glucose M2
Carbotone; Diabetes FoodMatrix™ Pack (the "Blood Sugar Pack")
"Carbotone"
NyGymnema Herbal Blood Sugar Balance
WSN® Diabetic Pack

Public Citizen's Health Research Group (HRG) has consistently advocated lifestyle changes such as diet and exercise as the primary the treatment for Type 2 (adult onset) diabetes. Six of the 12 oral diabetes drugs listed in HRG's book *Worst Pills, Best Pills* are categorized as Do Not Use drugs. You can find more information about these drugs and *Worst Pills, Best Pills* online at www.worstpills.org.

The New York City Department of Health's Recommendations for Living with Diabetes

People can reduce their risk of developing diabetes by 60% with:

- **Regular exercise** (30 minutes per day on most days)
- **Weight control** (Adults should try to keep their body mass index [BMI] under 25, the threshold for being classified as overweight.*)

Adults with diabetes can prevent heart disease, kidney disease, blindness, and amputations by:

- Not smoking
- Knowing and controlling their "ABCs." All people with diabetes should keep their
A1c level below 7%
Blood pressure less than 130/80
Cholesterol ("bad" LDL cholesterol) less than 100
- Controlling their weight and exercising
- Keeping their BMI under 25
- Exercising 30 minutes per day on most days
- Undergoing annual eye and foot examinations and practicing daily foot care
- Getting an annual flu shot and a one-time pneumonia shot (If a pneumonia shot was given before age 65, check with your doctor about a one-time revaccination.)
- Getting tested for kidney disease

* To calculate your BMI, visit <http://nhlbisupport.com/bmi/> or ask your doctor. As an example, a man of 5'10" would be overweight (BMI>25) if he weighed 175 pounds. Similarly, a woman of 5'4" would be overweight if she weighed 146 pounds.

Product Recalls

September 20, 2006 — October 20, 2006

This chart includes recalls from the Food and Drug Administration (FDA) Enforcement Report for drugs and dietary supplements, and Consumer Product Safety Commission (CPSC) recalls of consumer products.

DRUGS AND DIETARY SUPPLEMENTS

The recalls noted here reflect actions taken by a firm to remove a product from the market. Recalls may be conducted on a firm's own initiative, by FDA request or by FDA order under statutory authority. If you have any of the drugs noted here, label them "Do Not Use" and put them in a secure place until you can return them to the place of purchase for a full refund. You can also contact the manufacturer. If you want to report an adverse drug reaction to the FDA, call (800) FDA-1088. The FDA Web site is www.fda.gov. Visit www.recalls.gov for information about FDA recalls and recalls issued by other government agencies.

Recalls and Field Corrections: Drugs — CLASS I

Indicates a problem that may cause serious injury or death

Name of Drug or Supplement; Problem; Recall Information

WellPatch® Cough & Cold Soothing Vapor Pads;
Misbranded; Use of the product on young children can pose health risks due to potential accidental ingestion. Lots FE02A (exp. date 5/31/2007), FE03A (exp. date 5/31/2007), FE04A (exp. date 5/31/2007), FE05A (exp. date 5/31/2007), FE06A (exp. date 5/31/2007), FE07A (exp. date 5/31/2007), FE08A (exp. date

5/31/2007), FE09A (exp. date 5/31/2007), FF01A (exp. date 6/30/2007), FG01A (exp. date 7/07/2007), FG02A (exp. date 7/31/2007), FG03A (exp. date 7/31/2007), FG05A (exp. date 7/31/2007), FH01A (exp. date 8/31/2007), FH02A (exp. date 8/31/2007), Mentholatum.

Recalls and Field Corrections: Drugs — CLASS II

*Indicates a problem that may cause temporary or reversible health effects;
unlikely to cause serious injury or death*

Name of Drug or Supplement; Problem; Recall Information

Amantadine Hydrochloride Capsules, USP, 100 mg; Failed USP Content Uniformity Requirements. Lot # 6B943, exp. date 08/2007. UDL Laboratories, Inc.

Bumetanide tablets, 2mg, Rx Only; Incomplete laboratory testing investigation. Lot # 138184A, exp. date 06/2007, Ivax Pharmaceuticals, Inc.

Levoxyl (Levothyroxine sodium tablets, USP) 112mcg, Rx; Subpotent: The tablets have the potential to fall below the manufacturer's potency specifications before their labeled expiration date. Lot # 053668, exp. date: 09/2006, King Pharmaceuticals, Inc.

Gilpizide tablets, 10mg, Rx Only; Incomplete laboratory testing investigation. Lot # 146630A, exp. date 01/2008, IVAX Pharmaceuticals, Inc.

Citalopram Hydrobromide tablets, 20 mg, Rx Only; Incomplete laboratory testing investigation. Lot # 131890B, exp. date 11/2006, IVAX Pharmaceuticals, Inc.

Metformin Hydrochloride Extended-Release tablets, 500 mg, Rx Only; Unidentified foreign matter. Lot # 141330A, exp. date 05/2007, IVAX Pharmaceuticals, Inc.

C O N S U M E R P R O D U C T S

Contact the Consumer Product Safety Commission (CPSC) for specific instructions or return the item to the place of purchase for a refund. For additional information from the Consumer Product Safety Commission, call their hotline at (800) 638-2772. The CPSC web site is www.cpsc.gov. Visit www.recalls.gov for information about FDA recalls and recalls issued by other government agencies.

Name of Product; Problem; Manufacturer and Contact Information

All-Terrain Vehicles. The nuts securing the tie-rod ends to the steering shaft of Kawasaki 2007 Model Year Bayou 250 All-Terrain Vehicles may not have been tightened sufficiently during assembly. If the nuts loosen during operation, the operator could lose steering control, posing a risk of crashing. Kawasaki Motors Corp., (866) 802-9381 or www.kawasaki.com.

Baby Changing Tables. If the zipper of the Cariboo™ Folding Changing Tables and Cariboo™ Bassinet Changers is misaligned, it can come apart and allow the cloth surface to separate, posing a fall hazard to the baby. Scandinavian Child, (888) 353-2229 or www.SCIchild.com.

Baby Cookie Monster Toy. The small felt fabric cookie attached to the Baby Cookie Monster Plush Toy's hand can be removed easily and ingested by young children, posing a choking hazard. The Betesh Group, (800) 986-1619 or www.sesameworkshop.org/recall.

Bicycle Light Batteries. ARC Lithium Ion Bicycle Light Batteries can overheat, posing a fire or burn hazard to users. GP Batteries International Ltd., (831) 645-1538 or <http://www.bikelights.com/Support/liion.htm>.

Bicycles. The 2005 R2.5 Model Carbon Fiber Bicycles and Bicycle Frames can loosen or separate, causing the rider to lose control, fall and be injured. Cervelo Cycles Inc., (866) 296-3137 or www.cervelo.com/R25recall.

Blower/Vacuums. A loose connection between the Black & Decker BV4000 Type 1 Blower/Vacs and an extension cord can cause overheating, posing a fire hazard. Black & Decker Inc., (866) 853-2138 or www.blackanddecker.com.

Carabiners. Carabiners used for climbing have a green button that acts as a safety mechanism to prevent unlocking. The recalled carabiners can unlock unexpectedly without pressing the green button, posing a fall hazard. Petzl America, (877) 807-3805 or www.petzl.com.

Coffee Brewers. The Starbucks Barista Aroma(tm) Stainless Steel 8-Cup Coffee Brewers have defective electrical wiring that can result in overheating, smoking, burning and melting, posing a possible fire hazard. Starbucks Coffee Company, (800) 453-1047 or www.starbucks.com.

Computer Batteries. Rechargeable, lithium-ion batteries used in ThinkPad notebook computers can cause overheating, posing a fire hazard to consumers. Sony Energy Devices Corp., (800) 426-7378 or www.lenovo.com/batteryprogram.

Desk Lamps. The plastic near the bulb of Ledu-Brand desk lamps can overheat and melt. This poses a burn hazard to consumers who could touch the hot plastic. Advantus Corp., (800) 771-0529 or www.advantus.com.

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Name of Product; Problem; Manufacturer and Contact Information

Exercise Machines. The selector pin for the weight plates of FreeMotion Cable Cross and Dual Cable Cross Exercise Machines can slip out of its slot if the edges of the pin are worn, allowing the weights to drop suddenly. Falling weight plates can hit consumers using the machines. FreeMotion Fitness Inc., (800) 201-2109 or www.freemotionsfitness.com.

Hooded Sweatshirts. "Candie's" Brand Children's Hoodie Sweatshirts with Drawstrings have a drawstring through the hood, posing a strangulation hazard to children. In February 1996, CPSC issued guidelines to help prevent children from strangling or getting entangled on the neck and waist by drawstrings in upper garments, such as jackets and sweatshirts. The Cayre Group, (800) 284-3023 or www.cayre.com.

Hooded Sweatshirts. Youth hooded sweatshirts have a drawstring through the hood, posing a strangulation hazard to children. In February 1996, CPSC issued guidelines to help prevent children from strangling or getting entangled on the neck and waist by drawstrings in upper garments, such as jackets and sweatshirts. Gildan Activewear SRL, (877) 445-3265 Ext. 4090.

Kids Bath Sets. Items in the Suave Kids Bath Set contain small parts that pose a choking hazard to young children. Additionally, some of the handles on the carrying case are long enough to pose a strangulation hazard. Also, the plastic carrying case poses a danger of suffocation. Almar Sales Co., (800) 251-2522 or recall@almarsales.com.

Mattress Covers. The terry cloth Protective Mattress Covers (PMCs), which were made to fit over the Dux top pads, do not meet the federal standard for flammability under the Flammable Fabrics Act. They pose a risk of burn injury to consumers if exposed to smoldering or burning cigarettes. Dux Interiors Inc., (888) 836-7556 or www.dux.com.

MULE Utility Vehicles. Kawasaki MULE utility vehicles could have been assembled with improperly manufactured steering knuckles that could break while the vehicle is in operation. This can cause a loss of steering control and cause a crash resulting in injury or death. Kawasaki Motors Corp., (866) 802-9381 or www.kawasaki.com.

Outdoor Gas Fire Pits. If the regulator hose for the propane cylinder of the outdoor gas fire pits contacts the burner during use, the hose can rupture, presenting a risk of a fire outside of the unit. Agio International, (800) 598-6532 or www.agio-usa.com.

Scuba Regulators. Over-tightening of the Yoke or Din retainer during annual servicing of Scubapro® MK 20 First Stage Regulators could result in a stress crack and failure of the regulator. If this occurs during a dive, air supply could be interrupted, posing a drowning hazard. Scubapro® USA, (800) 731-6685 or www.scubapro-uwatec.com.

Snow Throwers. If the Two-Stage Compact Snow Throwers' tires are over-inflated, the plastic wheel rims can burst, posing a risk of lacerations and fractures. MTD Products Inc, (888) 848-6038 or www.mtdproducts.com.

Tents. All 2006 Quechua Brand Tents and Canopies may fail to meet the industry's flame resistant standard, posing a fire hazard. Decathlon USA, (888) 446-5147 or www.decathlon-usa.com.

Toy Trucks. The plastic wheels on LEGO EXPLORE Super Trucks can detach, exposing a metal axle. This poses a puncture hazard to young children. LEGO Systems Inc., (800) 718-1858 or www.LEGO.com.

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THE PUBLIC CITIZEN HEALTH RESEARCH GROUP

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The Health Research Group was co-founded in 1971 by Ralph Nader and Sidney Wolfe in Washington, D.C. to fight for the public's health, and to give consumers more control over decisions that affect their health.

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Diabetes in the U.S.: The Epidemic in Numbers

9.4 Percent	The proportion of adults 20 years old and older with diabetes, diagnosed and undiagnosed
2.4 Percent	The proportion of adults 20 years old and older with undiagnosed diabetes
27.1 million	Number of annual visits to office-based physicians due to diabetes
7.9 Percent	The proportion of patients in home health care with diabetes as a primary diagnosis
17 Percent	The proportion of nursing home residents with diabetes
357 days	Average length of stay for nursing home discharges with diabetes as primary diagnosis
#6	Rank of diabetes as cause of death

Source: National Center for Health Statistics, Centers for Disease Control and Prevention, <http://cdc.gov/nchs/fastats/diabetes.htm>

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included nearly 5,300 adults from clinics in 21 countries. These were randomly assigned to receive either Avandia or a placebo over the course of three years. All of the participants were at high risk of developing type 2 diabetes, having shown signs of poor blood-sugar control. The trial found that 280 persons (12 percent) taking Avandia developed type 2 diabetes, compared to 658 (26 percent) of those who took the placebo. In terms of risk reduction, the data indicate that, for every seven high-risk persons prescribed Avandia for three years, one will be prevented from developing diabetes.

Absent from much of the glowing press coverage of the DREAM trial was the fact that a better diet and getting more exercise are very effective non-pharmacological interven-

While interesting, the results of the DREAM trial are not a breakthrough. At present, lifestyle modification is the closest thing we have to a “magic bullet” in the prevention and delay of diabetes.

tions. Indeed, a study published in 2002 found that modifying risk factors with a sustained lifestyle intervention program was more effective than drugs in preventing type 2 diabetes: the lifestyle intervention lowered the incidence of type 2 diabetes by 58 percent, compared to a 31 percent reduction among those that received drug treatment. The effects were similar in men and women and in all racial and ethnic groups. But the lifestyle change strategy does not sell drugs — it actually reduces drug sales — and the only one who profits is the patient.

At the same time, the researchers found what they called a “small excess” in non-fatal cases of congestive heart failure with Avandia. This “small excess” amounted to a highly significant seven-fold increase in

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confirmed cases of heart failure in those taking rosiglitazone compared to the placebo group. In addition, there was an almost significant 37 percent excess in the rosiglitazone group of what the authors called "cardiovascular events composite," comprised of heart attacks, strokes, cardiovascular deaths, heart failure, the appearance of new angina attacks and the need for heart surgery such as bypass or angioplasty.

In addition to raising the inevitable question *Cui bono?* (To whose benefit?), the results of the DREAM trial raise questions concerning the ends of medicine. The people who were given ramipril and rosiglitazone in the DREAM trial were not sick. Those who were eligible to participate had to be at least 30 years of age and could not have a history of diabetes or cardiovascular disease or be intolerant to drugs in the same families as ramipril and rosiglitazone. The participants had elevated blood sugar levels but not to a level that would result in a diagnosis of diabetes; instead, they were labeled with a "new" illness: pre-diabetes.

There are perverse incentives for drug companies to develop new illnesses that can be treated with a drug that is patent protected. Legally, a company can promote a drug only for its Food and Drug Administration (FDA)-approved uses. This of course limits the size of the potential market. Level stock values and flat dividends drive investors to look for new opportunities. In order to keep investors happy, a company must grow the market, even if it means inventing a new disease to sell more drugs. Expanding the boundaries of an illness such as diabetes has been called "disease mongering," which was the subject of several recent articles in the *Health Letter*.

It is one thing to give a drug with known adverse effects to patients with a serious illness like diabetes,

but quite another to give the same drug to prevent the disease in otherwise healthy people. If a drug is going to be given to healthy people for disease prevention, it should be held to a high standard, and should be almost totally free from causing serious adverse drug reactions.

In 2000, Public Citizen petitioned the FDA to add warnings to the professional product labels or package inserts of rosiglitazone and the other drugs in the same family because of safety concerns about heart function, fluid retention, weight gain, anemia, and liver toxicity. The findings of the DREAM strengthen the rationale for these concerns.

The author of an editorial commenting on the results of the DREAM trial published in *The Lancet* on October 7, 2006, poses a very important question: "Is the lowering of blood sugar levels the same as preventing diabetes?" Because rosiglitazone lowers blood sugar, though modestly, it is approved by the FDA to treat type 2 diabetes. But the key question that remains unanswered by the DREAM trial is whether rosiglitazone prevents the onset of type 2 diabetes or simply lowers blood sugar levels in patients with new onset diabetes. At this time, we do not know the answer to this question.

A recent article in *The New York Times* underlines the superiority of lifestyle modification. At the same time, the article points out that lifestyle changes are frequently unsuccessful. Patients find it difficult to overhaul ingrained habits. And even those that do often have problems sustaining the changes over the longer term. Effective treatment is often delayed for years because of failed attempts at self-regulation through diet and exercise; during that time, patients' bodies have been damaged by the disease, increasing their risk of cardiovascular disease, among other things. Health authori-

ties once recommended lifestyle changes first, but international treatment guidelines were unfortunately modified last August. These recommendations that patients with abnormally high blood sugar levels begin taking medication immediately. This, despite the fact that medication is always less effective than properly-maintained lifestyle changes.

While interesting, the results of the DREAM trial are not a breakthrough. At present, lifestyle modification is the closest thing we have to a "magic bullet" in the prevention and delay of diabetes. For all the misgivings concerning the difficulties of behavior modification in the areas of diet and exercise, there is no question that, done and sustained, these interventions are more efficacious, probably cheaper, and are potentially accessible to all. Moreover, their effects can last a lifetime, and they can protect against other diseases as well.

Emphasizing this point, the above-mentioned editorial in the October 7th *Lancet* following the publication of the DREAM study stated that:

Overall, despite the impressive risk reduction for progression to diabetes, the lack of data on long-term benefits and side-effects, and the high cost of therapy, mean that health-care funders are unlikely to see rosiglitazone as an appropriate agent for individuals with impaired glucose regulation but low absolute cardiovascular risk. Given the prolonged benefits and demonstrable cost effectiveness of intensive lifestyle intervention for people at high risk of diabetes, **such interventions should remain the mainstay for the prevention of type 2 diabetes.** (emphasis added) ■

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Placing the Promise of Prevention in Context: The Case Against the Diabetes Drug Rosiglitazone (AVANDIA)

Many a small thing has been made large by the right kind of advertising.

— Mark Twain

“A Connecticut Yankee in King Arthur’s Court”

Last September, an orchestrated media blitz proclaimed that the diabetes drug rosiglitazone (Avandia) can prevent type 2 diabetes. This finding, hailed as a breakthrough in some reports, was based on the results a large clinical trial with the catchy acronym DREAM (Diabetes Reduction Assessment with Ramipril and Rosiglitazone Medication). The finding was announced amidst fanfare by a team

of Canadian researchers at an international meeting in Copenhagen, Denmark. On the same day, the DREAM results appeared on the Web site of *The Lancet*, a highly regarded British medical journal.

The DREAM study looked at both the diabetes drug rosiglitazone (Avandia) and the heart drug ramipril (Altace). The part of the DREAM trial that examined the blood pressure-lowering drug ramipril was eclipsed

by the media attention focused on rosiglitazone. At-risk patients who were given Altace fared no better than those taking a placebo. The researchers therefore concluded that ramipril did not forestall the disease in at-risk patients, although it did have some modest effect in lowering blood sugar.

The arm of the DREAM study that focused on rosiglitazone (Avandia)

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