

Health Letter

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Lost in Translation:

Why the Highly-Touted Dutch Health System Would Not Be a Good Idea for the U.S.

Recent interest in the Dutch health care system has been expressed by Michael Leavitt, Secretary of the U.S. Department of Health and Human Services (HHS), who visited the Netherlands in order to learn about their system, and by Senators Wyden (D-OR) and Bennett (R-UT), who recently introduced the Healthy Americans Act, based heavily on the Dutch system. These American leaders, in their enthusiasm for copying what is going on in the Netherlands, seem to have given inadequate thought to the current realities and serious problems of the Dutch system and the factors that make its comparison with ours inappropriate.

All health care systems perform three functions: they pay, purchase and provide health services. Decisions that affect payment and purchase generate the most legislative interest because they involve money and power and have more obvious “winners” and “losers.” But it is the way in which services are provided that most affects health outcomes. Beyond the questions of who should pay for whom, looms the query: are the services worth paying for? In the U.S. there is now wide consensus that the health care system is broken. It is too fragmented (the source of errors and inefficiencies), excludes too many and costs too much. Payment — whether multiple or single, public or private, redistributive or regressive — is important for the economic health of the body politic, but it may not solve issues of how services are delivered. Indeed, generous financing

of services that are intrinsically flawed may only reinforce the system’s deficiencies. Only when the payment and purchasing systems are used to leverage changes in the delivery of care will the U.S. have a more equitable, accountable and patient-centered system.

This reality, however, is often obscured in international comparisons. It is happening now as the U.S. looks to the Netherlands as a possible model for health reform. Unlike the U.S., where there is wide consensus that few are getting value for money in health care, the Dutch had a system that was widely popular and not particularly expensive. Health reform in the Netherlands was therefore not designed to fix a broken system, but to make a good system better: more equitable and responsive to those it served.

Interestingly, the Dutch picked up some of the ideas that were debated in the U.S. in 1994, when the Clinton administration designed a national

health care plan based on “managed competition.” It is worth recapping the recent history of the Netherlands plan, including its aims and the basic concept on which it is based. We will also discuss how the system has fared to date.

“Managed competition,” which we have renamed “mangled competition,” is an idea first proposed by U.S. economist Alain Enthoven in 1978. Committed to both bolstering market forces in the health care sector and covering everybody, Enthoven’s strategy was based on five principles: giving consumers a choice among plans, incorporating incentives for consumers to opt for efficient services, providing comparable benefits across plans (so that they would compete on price), risk-adjusting premiums to avoid cream-skimming and creating a single regulatory entity to level the playing field among competitors. In Enthoven’s words, managed competition sought to “reward with

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more subscribers and revenues those health plans that do the best job of improving quality, cutting costs and satisfying patients.”

While major aspects of the Enthoven plan were incorporated into the U.S. plan that was eventually proposed by the Clinton administration, the plan was vigorously opposed by the insurance industry, which feared any regulation that would curtail its business practices. Their strong campaign of TV ads soon became emblematic of how money could shape policy by controlling visual and verbal messages. Through the concerns voiced by its characters “Harry” and “Louise,” the insurance lobby effectively undermined the debate on health reform. With no countervailing power base to fight the insurance juggernaut, the Clinton plan fizzled. In the Netherlands, however, the insurance industry appears to have bought into “mangled competition” because it does not drive them out of business and because as discussed below, they still retain an unhealthy 30 percent of premium dollars.

Ideas, like gifts, can be rewrapped and presented anew, and Enthoven found a more receptive client in the government of the Netherlands. Intent on reforming their health care system to provide basic uniform coverage for all its citizens, the Dutch wanted to eliminate the distinctions in coverage between those who were covered by social insurance and those who had private coverage. They also wanted to contain costs, increase choice, improve efficiency and quality and maintain access. After many years of debate and discussion, they have adapted and adopted Enthoven’s ideas. The system that went into effect in January 2006 has elicited much commentary and analysis. Interestingly, these developments have piqued the interest of U.S. policymakers as mentioned above.

Health Care in the Netherlands

Unlike the U.S., in which the services are largely orchestrated by

consumers, if at all, and many patients have access to specialists directly, the Dutch system is firmly grounded in the primacy of primary care: family doctors are the point of entry and source of continuing care for most of the population. Family doctors are mostly self-employed and have historically served as gatekeepers to other services. This tradition of having a “medical home” means that, unlike in the U.S., practically everyone in the Netherlands is linked to a family physician and practice. The importance of this cannot be underestimated: primary care physicians, whether practicing individually or in teams, value prevention over cure and insure that priority is given to continuing, rather than episodic, care. Moreover, they orchestrate referrals, thereby conserving scarce resources and keeping track of the array of services provided to their patients.

In contrast, data for the U.S. indicate that nearly one-third of adults and more than half of all children lack a primary care “medical home.” Another distinction is that Dutch medical specialists tend to work in hospitals, most of which are private and non-profit. Hospitals have negotiated annual budgets which include specialists’ payments. A third basic difference is the extent to which the Dutch rely on nurses to deliver care: the Netherlands has 12.8 nurses per 1000 population, while the U.S. has only 7.9.

These fundamental differences are closely related to other aspects of the two systems, including their expenditures. While the U.S. spends 15 percent of its GDP on health care and leaves close to 50 million uninsured, the Netherlands spends 9.8 percent and only a very small fraction of its citizens are uninsured. Total expenditure per capita is \$5,635 in the U.S., and \$2,976 in the Netherlands.

The two systems coincide in their historical co-existence of private and public systems, and in their multiplicity of payers, including private insurers. But this shared financial overlay should not be overstated, and should

not eclipse the fact that the Dutch have a fundamentally different tradition of access to basic care, and have organized their system to facilitate coordinated, patient-centered services anchored by strong primary care. While much is made of the fact that the population of the U.S. numbers 300 million and is spread over a continental land mass while that of the Netherlands is only 16.6 million inhabitants densely packed into a compact territory, the differences in scale are less important than the differences in attitudes toward the importance of health care and its organization. Like politics, most health care is local: systems can therefore be scaled up or down, with self-contained health care regions having functional autonomy even when the collection and distribution of revenues is centralized.

The Goals of Health Reform in the Netherlands

Concerns over equity and a desire to broaden consumer choices in their health insurance arrangements were the main drivers behind health reform in the Netherlands. Before the current changes, the Netherlands had a two-tier system in which almost two-thirds of the population had compulsory social insurance, while the remaining third had private insurance. Coverage depended on a person’s employment, income, age and health status. These distinctions have been eliminated: coverage has been standardized and everyone must play by the same rules.

The new system mandates coverage for all. It has also modified the roles of all participants in the system: consumers, employers, providers, insurers and the government. All stakeholders have some latitude for action at the same time that most activities take place in a highly regulated environment. Over the longer term, the system seeks to make trade-offs transparent and foster decisions that are both medically sound and economically rational. These goals require major changes, some of which are still in process.

The Changing Functions of Stakeholders

The Role of the Consumer

Each Dutch citizen over the age of 18 is required by law to buy individual health insurance from the insurer of his or her choice. For this, the consumer now pays the insurer an annual flat rate premium averaging approximately \$1780 (The current premium is 1200 Euros, the exchange rate being \$1.00= 1.48 Euros). In addition, each individual pays a tax pegged to his or her income to help subsidize the premiums for low-income groups. Those with yearly incomes under \$35,600 can expect a subsidy. Taxes also help pay for those under 18 and for plans that are serving sicker (and therefore costlier) patients. These taxes redistribute resources from adults to minors, as well as from the affluent and healthy to the poor and the sick. Although data on performance are not yet in, the expectation is that the major beneficiaries of the reform will be the elderly, the chronically ill and families with children. Conversely, families without children, singles and retirees are likely to be paying more for health insurance than they were in the past.

Consumers cannot opt out of the national health plan, but they can choose among different insurers. Because the service package is uniform, choice is based primarily on price. In addition, consumers can choose between cash benefits, in-kind benefits or a combination. They can choose between an individual and a group plan, the latter being more affordable. They can also decide whether or not to choose a voluntary deductible of up to \$740 per year; in return, they receive a premium discount. Consumers must also decide whether or not to purchase supplemental coverage beyond the mandated service package. They can decide whether to stay with their insurers' preferred providers or select care out-of-network, the latter entailing an extra expense. Consumers can also obtain ambulatory care in another European Union country from a non-contracted provider.

Consumers can switch plans once a year if they are not satisfied. The expectation was that, because health insurance is "sticky," patients would tend to stay with their initial choices. But the early experience has been that Dutch consumers "vote with their feet" and do indeed switch plans. Within the first year, 21 percent of all enrollees opted to change insurers. An additional 14 percent kept the same insurer but chose to take out another policy. This degree of mobility was seen as both an indicator of dissatisfaction and as a vindication of consumers' ability to respond to prices and exert their purchasing power.

Those over 18 years of age who do not use any health care in a given year are entitled to a no-claim rebate of \$377 at the beginning of the following year. Those who have claimed an amount under this ceiling are entitled to the difference between their claim and \$377. Visits to a primary care doctor, and prenatal and maternity care, are not counted towards the no-claim rebate. The rebate provision, which predates the health care reform, is intended to curtail unnecessary demand. Nevertheless, it can also be a deterrent to needed care, and discriminates against the chronically ill. For example, some who were severely sick did not go to the doctor, gained their rebate, but got sicker, thereby costing the health system more in resources and treatment. In 2005 (prior to the health care reform), 53 percent of those insured received some part of the rebate; 18.5 percent received the rebate in full. Because of its extremely inequitable features, the rebate was scheduled to end in January 2008.

Employers' Involvement

Employers play no role vis-à-vis insurers; however, they contribute to the system's revenues by reimbursing employees for their contributions. This reimbursement is taxable to the employee. Employers can also opt to cover supplementary benefits, which are also taxable to the employee. In order to obtain the support of

employers for the reform, their increased financial burden was offset by lower corporate taxes; thus the scheme is largely budget-neutral to employers.

The Providers' Responsibilities

Physicians practice under contracts negotiated with private insurers. Family doctors earn a set payment for each patient on their practice list and a fee per consultation. Specialists are self-employed but hospital-based, and are also paid on a salaried or capitated basis. Their fees are also based on negotiations with insurers.

One of the aims of the Dutch health care reform was to encourage providers to behave efficiently and compete effectively on the basis of value for money. The idea was that insurers would then steer patients towards those providers that were the most efficient and, presumably, effective. This in turn requires collecting and disseminating information on the quality of services, which is not currently available. Nevertheless, government and private organizations are now working on this aspect of the scheme. The goal is for providers to "work in a more performance-oriented way" at the same time that they will have more opportunities to distinguish themselves.

Regulations have been modified to encourage competition within the provider market. Legal barriers to new entry were liberalized and many independent clinics entered the market.

The new scheme has also modified the way in which hospitals are paid. The introduction of a system based on cost-per-treatment seeks to facilitate negotiations between hospitals and insurers. This system is being implemented gradually. During the first year, both parties negotiated on volume, price and quality of about 10 percent of hospital services; this share will rise to 20 percent in 2008 and increase gradually thereafter.

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The Role of Insurers

Insurers are caught between the state's desire for uniformity to insure equity in access to care and the variety required for competition and meaningful consumer choice. Unlike the situation in the U.S., insurance companies in the Netherlands operate within a stringent regulatory apparatus that defines their products, scope of operations (i.e., they must be nationwide, or include one or more entire provinces if they are small), purchasing agreements and reporting requirements. At the same time, they can be for-profit entities that pay dividends to shareholders.

Health insurers have to offer a basic benefits package for which consumers pay a nominal premium equivalent to half of total expenditures; the other half is covered by income-dependent contributions that the state pays to the Health Insurance Fund.

Because they all offer the same coverage, insurers compete on the basis of price and "extras." They can offer discounts of up to 10 percent for group rates, and provide additional price breaks for those who opt for a voluntary deductible. Insurers also compete on the basis of different supplementary packages, service levels, and different types of preferred provider networks. The mass media play an important role in pointing out these differences, and the different insurers rely on advertising to distinguish their offerings and entice buyers to choose their products. A total of \$103.6 million are estimated to have been spent on advertising.

Supplementary packages cover services beyond those mandated, allowing those who want to avoid additional risks or need special care to get greater coverage. Some packages target particular demographic groups (adolescents, the elderly), diseases (e.g., diabetes) or extend services that are capped or restricted in the basic coverage (e.g., physical therapy, dental care). Supplementary insurance is voluntary, and insurers can select which risks to cover. These additional services are deemed

important by most consumers: more than 90 percent of the population has bought supplementary insurance.

In sharp contrast to the situation in the U.S., insurers are not allowed to exclude any potential buyer, nor can they charge different premiums based on age, medical history or health status. But because some insurers may nevertheless run the risk of adverse selection — attracting those with higher-than-average risks of ill health who use services more intensely — the Netherlands system has adopted a "risk equalizer" program to compensate insurers who bear a disproportionate share of high-risk patients. This feature, together with the uniform basic health insurance package, is intended to remove those selection incentives for companies that would otherwise engage in cream-skimming of healthier patients in order to maximize their profits.

Insurers must provide for health care, and can decide when and by whom health care will be delivered. They thus engage in selective contracting with providers, and can choose to drop any provider that is not seen as a desirable partner. Some insurers are instituting incentives to bolster quality, particularly in the area of primary care services. Two major insurers have incorporated pay-for-performance measures. These allow primary care practices to earn a 10 percent bonus in their income for complying with quality indicators. In addition, one insurer has instituted financial incentives to promote physician prescribing of the cheapest generic drugs. This strategy was contested in court, but the court judged in the insurer's favor.

Because insurers have a vested interest in consumers assuming greater responsibility for their health, they are disseminating information on health promotion and disease prevention. They also let their customers know about the availability of fitness clubs, nutrition counseling and other supportive services, and may even partly cover the costs of these.

State Interests and Functions

Although ostensibly market-driven, the Dutch system is importantly based on a strong regulatory framework that seeks to balance the health system's contradictory objectives. This is in keeping with Enthoven's acknowledgement that consumer sovereignty and simple market competition will not automatically result in health resources being allocated efficiently because of information asymmetry (i.e., some of the involved parties having more or better information than others) and professional dominance (physicians and other providers having the upper hand in many decisions concerning health care). Regulation is needed to ensure the conditions under which the market can function without sacrificing universal access to affordable care. The state therefore retains stewardship of the system and establishes the rules within which all the players must function; its purview includes safeguarding quality, accessibility and affordability of care. This in turn requires performing the following tasks:

Defining basic coverage: The government decides the content and scope of services to be included in the basic package for all citizens. Services must meet criteria of demonstrable efficacy, cost-effectiveness and the need for collective financing. At present, the package includes hospitalization, surgery, physician fees, prescription drugs, chronic illness and basic dental health care. Services such as physiotherapy, psychological care and complicated dental procedures are not included; these may be covered through supplementary policies. The short-sighted leanness of the Dutch benefits package is strikingly exemplified by the lack of coverage for psychological care. This important component of health care would have to be purchased as an "extra," seriously discriminating against those of lesser economic means.

Collecting and distributing revenues: The state determines the level and type of contributions

required by consumers and employers for the financing of the health insurance system. It also sets the health care allowance based on the enrollee's income. The state currently subsidizes some 30 percent of the population, those whose incomes would not allow them to comply with the insurance mandate. The state also imposes fines for those that are uninsured; these are 130 percent of the premium.

Establishing modalities of provider payments: In addition to regulating hospital payments, the state also exerts an influence over other providers. For example, the system protects patients from paying a penalty for using a physician who is not under contract with their insurer by controlling how much this physician is paid vis-à-vis within-network providers. In addition, the government exerts its purchasing power by negotiating with generic drug manufacturers; these have lowered their prices by about 40 percent.

Leveling the playing field for insurers: Risk equalization is considered essential to protect insurers against the unequal distribution of insurance risks. This mechanism seeks to create a safety net for insurers, entitling them to extra compensation for expensive customers who have higher risks. Additionally, the state acts as a "market referee," ensuring "that negotiations between insurers and care providers are honest" and that there are checks against creating monopolies and power blocs.

Providing incentives for prudent use of services: As previously discussed, consumer rebates are aimed at deterring frivolous use of services. At the same time, they exclude expenses incurred for services that the system wants to encourage (e.g., primary care and prenatal and maternity services). Due to its inequitable features, this rebate was scheduled to be phased out in 2008.

Monitoring care: Consumer choice is one of the cornerstones of the Dutch system. Therefore, the government recognizes that "the insurance market has to be

transparent for all those involved" and therefore pursues certain policies to meet this objective. The government plans to use "report cards" to make it easier to compare health insurance companies with each other. In the meantime, a number of stakeholders have developed competing and overlapping performance indicators, a situation that has created confusion among those who collect the data.

Persistent Issues

The health system in the Netherlands seeks to make social solidarity compatible with private enterprise and the business of health care. As the Dutch struggle with the delicate equilibrium between individual decision-making and private insurance, on the one hand, and equity in access, on the other, they face trade-offs that may strengthen one or the other. It is therefore not surprising that health reform in the Netherlands faces continuing challenges. Here, we summarize some of the issues that are still on the agenda.

Who is left out?

At present, the Dutch system is not universal. Non-residents, including illegal immigrants, have access to emergency care and can obtain other health services at their own expense, but have no right to basic health insurance. This is an issue because some of the affected are immigrants who were denied asylum on unjust grounds (i.e., when the government made a decision that it was safe for them to return home), and are, in effect, people without a country. Another group that is excluded comprises bad debtors who have not paid their premium. If their debt exceeds five years, other insurers can also refuse to cover them; they therefore remain outside the system.

How much coverage is enough?

What benefits to cover is a crucial aspect of any health care scheme. In order to bolster competition in private insurance, the Dutch have restricted their mandated benefits, excluding

some services for which consumers are willing to pay supplementary, gap-plugging premiums. The fact that more than 90 percent of enrollees have some supplementary policy suggests that the basic package is seen as deficient, and that the vast majority of consumers are willing to pay an additional fee to get broader coverage. But expanding the basic coverage would limit the add-on plans which the insurers now sell, and would therefore encroach on the private market which the state is trying to enhance.

Does supplementary insurance undermine equity?

The leaner the basic package, and the greater the need for supplementary coverage, the more likely the health plan will result in disparities for consumers. While most Dutch citizens have found it desirable and feasible to buy additional insurance, those that do not are likely to be those who perceive themselves as healthier, or who lack the discretionary income to protect themselves against additional risks.

The very existence of supplementary insurance makes health care a purchasable commodity and seriously undermines equity. To put it in other words, as long as some have to settle for bread and butter while others also get jam, equity is compromised.

How many sellers are needed to ensure competition?

The Dutch system is premised on increased consumer choice. This was the rationale behind allowing multiple insurers into the system. Over time, however, the number of insurers has dwindled and the concentration of consumers opting for a handful of plans has increased.

Reforms triggered a premium war, with price competition becoming "very fierce" and creating an interesting dynamic. Some insurers offered "loss leaders" in order to make their products more attractive vis-à-vis the competition. They therefore priced their premiums below the break-even point in order

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to entice customers, hoping to offset their losses by selling more lucrative supplemental coverage. But because it was the larger insurers that had the financial reserves to cushion the initial losses, the smaller insurers were squeezed out of the market. As a result, the number of insurers has decreased dramatically from 41 in 2006, when the plan was enacted. Two of the largest health insurers merged in mid-2006, giving one insurer 50 percent of the health insurance market. Subsequent mergers have reinforced the trend towards consolidation: 22 insurers have reconfigured themselves as four conglomerates, and these account for 80-90 percent of the total market. This has limited the consumer options that the reform intended to promote. Any further consolidation will result in oligopoly and negate the very idea of choice that the system sought to enhance.

Have costs been contained? Is the system more efficient?

The effect of the reform on costs is difficult to estimate. Because insurers set their premiums artificially low and thus suffered initial losses in order to consolidate their market share, higher-than average increases followed the initial shakeout in the insurance market. Consumers therefore faced premiums that increased 10 to 12 percent going into year two of the reform.

In addition, because the system relies on multiple payers offering a basic package with variations (different levels of deductibles, individual vs. group, closed panel vs. open choice of providers, etc.), and enrollment can be modified once per year, Dutch insurers face the same administrative costs that most private insurance enterprises incur:

costs associated with advertising and marketing their basic offerings and their supplementary coverage; transaction costs involved in enrolling and de-enrolling members; monitoring utilization and provider costs; and reporting to stakeholders and the state. Of course, private plans must factor in their profits. As a result of these expenses, the insurers' "loss ratio" — reflecting the share of premiums that is actually paid out as benefits — is unacceptably low in the Netherlands. (While the loss ratio may be subject to accounting manipulations and cannot be construed as an indicator

of efficiency, it at least allows for inter-plan comparisons).

Unofficial data for the first year suggested that insurers' costs approached 30 percent, which is considered extremely high. This means that the loss ratio is 70 percent (that is, only 70 percent of the premiums are paid out in benefits), the rest going for administrative costs and profits.

Interestingly, this figure is not dissimilar to the highest estimate for administrative costs for the U.S. health system as a whole. Well over \$350 billion a year in excessive administrative costs have been one of the main factors financially disabling our multi-payer system. The Dutch seem to be facing some of the same problems, due, in large measure, to the waste and complexity guaranteed in a system with multiple payers, multiple premium levels, etc.

Are consumers satisfied?

Because the system is still new and has been subjected to some adjustments, it is early to assess consumer satisfaction with the scheme. One poll, however, showed that consumers are largely dissatisfied: they feel that choosing

a policy has become more difficult, and perceive quality as being lower. Forty-one percent of those surveyed said quality was lower, while 8 percent thought it had improved. Still, it must be recognized that the Dutch health care system has been traditionally well-regarded by the patient population, and that reservoir of goodwill is not easily eroded. In 2005 the Netherlands was the top scorer in the Euro Health Consumer Index, which ranks the national health systems of European countries from the patient/consumer point of view. Two years later — and based on a more comprehensive index with different indicators — the Dutch system had fallen to second place, outranked by Austria.

In Short

Any two health systems are compare-able. But this does not mean that they are comparable. As long as the Netherlands is unfortunately being suggested as a model for the U.S., it behooves us to be better informed of the key differences that distinguish the Dutch from the U.S. health care system. We should also be attentive to the values embedded in the Netherlands reform, and to the shortcomings that are only now being documented and possibly addressed.

We continue to strongly support a single payer health care system for the United States which would not only avoid massive administrative waste but could also compel the reorganization of delivery. A model for this reorganization, into pre-paid, non-profit, multispecialty practice groups centered on the provision of primary care, has been outlined by former *New England Journal of Medicine* Editor Dr. Arnold Relman in his recent book, "A Second Opinion: Rescuing America's Health Care."

The U.S. can only have a more equitable, accountable and patient centered system if we adopt a single payer system that leverages changes in the delivery of care.

Product Recalls

December 15, 2007 - January 14, 2008

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

Desirin Dietary Supplement Capsules, Phyto-Pharmaceutical Solutions for Female Sexual Function, packaged in a blister pack of 15 capsules to a box, 204 blister packs; Unapproved New Drug; product found to contain active pharmaceutical ingredients and analogs of FDA-approved drugs used to treat erectile dysfunction (ED). 02/07 02B07 X02/10, TWC Global, LLC.

Axcil Dietary Supplement Capsules, Phyto-Pharmaceutical Solutions for Male Sexual Function, packaged in a blister pack of 15 capsules to a box, 204 blister packs; Unapproved New Drug; product found to contain active pharmaceutical ingredients and analogs of FDA-approved drugs used to treat erectile dysfunction (ED). 02/07 02B07 X02/10 TWC Global, LLC.

Energy Max Energy Supplement ® Men's formula Natural Herbs, 20 Vege Capsules, Approx 28,958 blister packs; Unapproved New Drug; product found to contain various analogues of FDA-approved drugs used to treat erectile dysfunction (ED). Product with the expiration date up to and including December 2010; H & L Industries, Inc.

True Man Sexual Energy Nutriment, Men's formula, Natural Herbs, 10 Vege Capsules, Approx 28,958 blister packs; Unapproved New Drug; product found to contain various analogues of FDA-approved drugs used to treat erectile dysfunction (ED). Product with the expiration date up to and including December 2010; H & L Industries, Inc.

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

Armour Thyroid (thyroid tablets, USP). 3-grain (180 mg), each tablet contains 114-mcg levothyroxine and 27-mcg liothyronine, 100 and 1000-tablet bottles, Rx only, 35,222/100-tablet bottles and 422/1,000-tablet bottles; Product failed disintegration specification at 6-months. Lots: 1,000-tablet bottles: 030732 exp. date 08/2008, 090724 exp. date 02/2009; 100-tablet bottle lot #: 030714 exp. date 07/2008; 050771 exp. date 07/2008; 030723 exp. date 08/2008; 050772 exp. date 08/2008; 040726 exp. date 10/2008; 040727 exp. date 10/2008; 070723 exp. date 11/2008; 070724 exp. date 12/2008; 090724 exp. date 02/2009; Forest Pharmaceuticals Inc.

Ketoconazole Shampoo, 2%, 4 fl. Oz., Rx only, 9348 units; Stability testing indicates product will be out of specification by 12 month time point (Subpotent). Lot # 2472; Tolmar, Inc.

Glyburide Tablets, 5mg, 100 tablet bottles, Rx only, 175,088 bottles; Glyburide Tablets did not meet dissolution specifications on stability. 10PUD exp. date 06/2009 100 count bottle; 51PWF

exp. date 10/2009 100 count bottle; 49PWF exp. date 10/2009 1000 count bottle; 50PWF exp. date 10/2009 1000 count bottle; 14PWX exp. date 11/2009 1000 count bottle; 96PKX exp. date 11/2009 1000 count bottle; 97PKX exp. date 12/2009 1000 count bottle; 28PXM exp. date 12/2009 500 count bottle; 83PXS exp. date 12/2009 500 count bottle; 82PXS exp. date 12/2009 1000 count bottle; OAAC7 exp. date 12/2009 1000 count bottle; OAAC8 exp. date 12/2009 1000 count bottle; C070414 exp. date 01/2010 1000 count bottle; C070411 exp. date 01/2010 100 count bottle; C070412 exp. date 01/2010 1000 count bottle; C070687 exp. date 01/2010 500 count bottle; C070682 exp. date 01/2010 1000 count bottle; C070683 exp. date 01/2010 100 count bottle; C070529 exp. date 01/2010 1000 count bottle; C070419 exp. date 01/2010 100 count bottle; C070420 exp. date 01/2010 500 count bottle; C070899 exp. date 05/2010 100 count bottle; C070901 exp. date 05/2010 500 count bottle; C070903 exp. date 05/2010 1000 count bottle; C070904 exp. date 05/2010 1000 count bottle; C070906 exp. date 05/2010 1000 count bottle; C070900 exp. date 05/2010 100 count bottle; C070902 exp. date 05/2010 500 count bottle; C070907 exp. date 05/2010 1000 count bottle; C070908 exp. date 05/2010 1000 count bottle; C070905 exp. date 05/2010

CONSUMER PRODUCTS

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 Drug or Supplement; Problem; Recall Information

Air Conditioners/Heat Pumps. Wires in the heater element of the Remington and McQuay "ComfortPac" Air Conditioners and Heat Pumps can overheat and spark, posing a smoke and fire hazard to consumers. McQuay International, (800) 377-2787 or www.mcquay.com.

ATVs. The pivot bolts holding the rear suspension onto the frame of the 2006-2008 Model Year MXU 500 All Terrain Vehicles can become loose, causing the rear swing arm to detach from the chassis posing a risk of injury or death to the operator. KYMCO USA, (888) 235-3417 or www.kymcousa.com.

ATVs. Water can enter the throttle position sensor of the Model Year 2007 Honda TRX 500 ATVs and freeze, causing permanent damage if the rider forces the throttle lever. This could cause the throttle to stick open, posing a risk of injury or death to riders. American Honda Motor Co., Inc., (866) 784-1870 or www.powersports.honda.com.

Bathroom Medicine Cabinets. The Medicine Cabinet's mirrors can separate and break, posing a laceration hazard. RSI Home Products, (888) 774-8062 or www.estatebath.com, www.insigniacabinets.com, www.masterbath.com.

Bicycle Helmets. The Specialized Bicycle Helmets fail testing required under CPSC's safety standard for bicycle helmets. This can pose a head injury hazard to riders in a fall. Specialized Bicycles, (877) 808-8154 or www.specialized.com.

Children's Trailer Bicycles. The coupler connecting the children's trailer bike to the adult's bicycle has welds that can fail, posing a fall hazard to children. These include InStep "Pathfinder," Schwinn "Run About" and Mongoose "Alley Cat" Trailer Bicycles. Pacific Cycle Inc., (877) 564-2261 or www.mongoose.com.

Christmas Candle Sets. The snowman candle in Christmas Candle Sets could tip over and the exterior coating on both candles can ignite, posing a fire hazard. Specialty Merchandise Corporation (SMC), (888) 839-8757 or www.smcorp.com/recall.

Coin Banks. Surface paint on the Fish Coin Banks contains excessive levels of lead, violating the federal lead paint standard. TJ Promotions, (866) 742-2493 or www.tjpromo.com.

Cordless Drills. The trigger switch of the DEWALT Cordless Drills can overheat, posing a fire hazard to consumers. DEWALT Industrial Tool Company, (888) 742-9168 or www.DEWALT.com.

Counterfeit Circuit Breakers. The Counterfeit Circuit Breakers labeled as "Square D" have been determined by Square D to be counterfeit and can fail to trip when they are overloaded, posing a fire hazard to consumers. North American Breaker Co. Inc. (NABCO), (866) 505-5851 or www.nabcorecall.com.

Digital Timers. The Intermatic DT27 Digital Self-Adjusting Timers could have been wired incorrectly, which poses an electrical shock hazard to consumers. Intermatic Inc., (800) 704-3595 or www.intermatic.com.

Electric Motors. The Whole-house Exhaust Fan Electric Motors can be miswired and overheat, posing a fire hazard. A.O. Smith Electrical Products Co., (866) 567-3878 or www.aosmithmotors.com.

Full Body Safety Harnesses. The Full Body Safety Harnesses could fail during use, resulting in a hunter falling from the tree stand and suffering serious injuries or death. Gorilla Inc. (877) 685-7817 or www.gorillatreestands.com.

Gap Boys' Jackets. The "Warmest Jacket" Boys' Jackets have a waist drawstring with a toggle that could become snagged or caught in small spaces or doorways, which can pose an entrapment hazard to children. In February 1996, CPSC issued guidelines to help prevent children from getting entangled at the waist by drawstrings in upper garments, such as jackets and sweatshirts. Gap Inc., (888) 747-3704 or www.gapinc.com.

Hand Dryers. Some of the nozzles on World Dryer and Bradley Brand Hand and Hair Dryers are not grounded. If an electrical component comes into contact with an ungrounded nozzle, it can pose a shock hazard to consumers. World Dryer Corp., (800) 323-0701 or www.worlddryer.com.

CONSUMER PRODUCTS

Hooded Sweatshirts. The Jewel brand girls' hooded sweatshirts have a drawstring through the hood, which can pose 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. Liberty Apparel Co. Inc., (212) 768-3030.

Lawn Mowers. The cutting blades of Honda Walk-Behind Lawn Mowers could rotate under power when the control lever is released. The lawn mowers do not comply with mandatory federal safety standards for lawn mowers. The spinning blade poses a serious laceration hazard to consumers. American Honda Motor Corp., (800) 426-7701 or www.hondapowerequipment.com.

Measuring Charts. The paint on the Giant Measuring Chart contains excess levels of lead, violating the federal lead paint standard. Discount School Supply, (800) 919-5242 or www.discountschoolsupply.com.

Mountain Bikes. The frame of Cannondale 2008 model year "Scalpel" mountain bikes can break while in use, causing the rider to lose control and suffer injuries from a fall or collision. Cannondale Bicycle Corporation, (800) 245-3872 or www.cannondale.com.

Pacifiers. These "BabyTown" Pacifiers fail to meet federal safety standards for pacifiers. The pacifier shield is too small and could easily enter the mouth of an infant. Also, ventilation holes are too small and not placed to allow for the insertion of a tool to remove the pacifier when lodged in the mouth of a child. Finally, the package fails to display the required warning instructing consumers not to tie a pacifier around a child's neck, which would present a strangulation hazard. Shims Bargain Inc., (866) 540-3334.

Pressure Cookers. If the Pressure Cookers are not closed properly, the lid can separate and allow hot contents to spill out. This poses a risk of burns to consumers. Mantra Inc., (877) 962-6887 or www.mantra.com.

Snowmobiles. A defect in the Ski-Doo® Model Year 2008 MXZ X 600 RS Snowmobile's carburetor can prevent the throttle from freely returning to the idle position. This can result in an unexpected loss of control leading to a collision and cause serious injuries or death. Bombardier Recreational Products Inc. (BRP), (888) 638-5397 or www.ski-doo.com.

"Soldier Bear" Toys. The surface paint on the Soldier Bear Toys contains excessive levels of lead, violating the federal lead paint standard. AAFES (Army & Air Force Exchange Service), (800) 866-3605 or www.AAFES.com.

Stuffer Bears. The neck medallion zipper pull of the Holiday Cosmetics Stuffer Bears can detach, posing a choking hazard to young children. Victoria's Secret, (877) 260-8419 or www.victoriasecret.com.

Super Magnet Toys. The Super Magnets attached to the bottom of a small toy panda can detach. If swallowed or aspirated by young children, the magnets can attract each other internally and cause intestinal perforations or blockages, which can be fatal. Man's Trading Company, (800) 388-7228 or email mtcmans@aol.com.

Teething Rings. The silver ball that holds the ring in place on the Sterling Silver Teething Rings can separate and release the beads inside. This poses a choking and aspiration hazard to infants. Empire Silver Company, (800) 255-9475 or www.empiresilver.com.

Tinker Bell Lamps. The surface paint on the Tinker Bell Lamps contains excessive levels of lead, violating the federal lead paint standard. Kash N' Gold Ltd., www.kngamerica.com.

Torchiere Lamps. A short circuit in the Portfolio Incandescent Torchiere Lamps' wiring can pose a fire hazard to consumers. L G Sourcing, Inc., (866) 916-7233 or www.lowes.com.

Toy Building Blocks. The firm has received two reports of the plastic covering detaching from the Tot Tower toy blocks and being mouthed by young children. No injuries have been reported. eeBoo Corp., (800) 791-5619 or www.eeboo.com.

Toy Wagons. Surface paint on the Metal Toy Wagon buckets contains excessive levels of lead, violating the federal lead paint standard. Tricam Industries Inc., (800) 867-6763 or www.tricam.com.

Warmer Dishes. Flames from the Covered Warmer Dishes with Rack's tea candle can extend up the sides of the dish. In addition, a label on the bottom of the dish causes excessive smoke when exposed to the flame. This poses fire and burn hazards to consumers. Lenox Group Inc., (800) 635-3669 or www.lenox.com/recall.

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The figure accompanying this article gives the details from the published study (PLOS Medicine, January, 2008) and we explain some of the categories.

Drug samples

are given by drug companies to physicians so they can get patients started on a new drug, later leading to large expenditures by patients and insurers on these usually quite expensive products. The study estimated that in 2004, \$15.9 billion

of such samples were given to doctors, making up 27.7 percent of promotional expenditures.

Detailing in this study includes the total cost of a sales representative's visit to a physician, accounting for the expenses of regional sales managers, promotional material handed out and the costs of training the sales representatives. The calculated expense for this was \$20.4 billion in 2004, making it the largest component, 35.5 percent, of promotional expenses.

DTCA (Direct To Consumer Advertising) needs no explanation since people in the United States are constantly besieged by it. Although it amounted to "only" \$4 billion in 2004 and made up just 7 percent of the total

promotional expenditures, it clearly works, roping in patients to ask their doctors for heavily advertised drugs, often relying on ads that overstate the benefits and minimize the risks.

Medical Meetings are those sponsored by drug companies and expenditures for these in 2004 were \$2 billion, 3.5 percent of promotional spending.

Unmonitored Promotion refers to promotional expenses that were not reported by the two companies providing most of the data for this

article. To gather information the authors surveyed doctors directly. This amounted to \$14.4 billion in 2004 and represented 25 percent of promotional expenditures.

The authors pointed out that these data may well underestimate total promotional expenditures by drug companies because of the unavailability of data from three types of well-documented promotional activities that companies would never admit to. First is the thriving business of companies getting professional journalists, who have not been involved in a study, to ghost-write often drug-favorable articles that appear under the names of real researchers. The second unmeasured category is illegal off-label promotion

of drugs, that is, promotion of Food and Drug Administration-approved drugs for treatments not approved by the agency. This has been the subject of massive fines against companies such as Pfizer for illegally promoting the painkiller Neurontin. The third is for so-called "seeding trials," in which, disguised as research, companies attempt to get more doctors used to using their drugs.

The finding that, as a percentage of U.S. domestic pharmaceutical sales in 2004, 13.4 percent went to research and development but 24.4 percent went to promotion is not consistent with the "research uber alles" image the industry tries to project. The authors of this study quote a recent book stating that the image of life-saving "researchers in white coats" was now contested by the one of greedy "reps in cars."

The pharmaceutical industry keeps beating the undocumented drum that controls on drug prices would stifle research and thus innovation, and they have successfully promoted a complicated, ultimately unworkable Medicare Part D to pay for drugs that disallows either negotiated or controlled prices. This study provides a well-documented reminder that the industry is much more financially committed to massive promotional expenses than to research and development of drugs.

"This study provides a well-documented reminder that the industry is much more financially committed to massive promotional expenses than to research and development of drugs."

THE PUBLIC CITIZEN HEALTH RESEARCH GROUP

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Drug Industry Spends Almost Twice as Much on Promotion of Drugs as on Research

Two Canadian medical researchers, Doctors Marc-Andre Gagnon and Joel Lexchin, have estimated that U.S. pharmaceutical industry marketing expenses in 2004 were \$57.5 billion dollars. This amount is almost twice industry expenditures for research and development of drugs (\$31.5 billion in 2004) and amounts to an average expenditure of \$61,000 per physician in promotion per year. This estimate is based on the most recent and reliable data available from two large international companies who collect information on the details of pharmaceutical company drug promotional expenses.

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Pharmaceutical Marketing Expenditures in the United States in 2004 (from Gagnon and Lexchin, PLOS, January 2008)

Type of Promotion	Estimate (US\$ Billions)	Percent of Total of Estimate
Samples	15.9	27.7%
Detailing	20.4	35.5%
DTCA	4	7%
Meetings	2	3.5%
E-promotion Mailing, Trials	0.3	0.5%
Journal Advertising	0.5	0.9%
Unmonitored Promotion	14.4	25%
TOTAL	57.5	100%

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