

# Health Letter

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## Medicaid@40: Why It Matters

Medicaid has been called many things:

- a remnant of the “poor-law” philosophy that made distinctions between the “deserving poor” and others in need,
- the cornerstone of the nation’s diverse and complex system of financing health and long-term services,
- a crucial safety net for those who need assistance with health care,
- a workhorse, expected to aid populations when no other source will help,
- an amalgamation of responses to different problems over 40 years,
- a surprisingly flexible program, and
- a rigidly inflexible and inefficient system that is not financially sustainable.

Whatever the prevailing contradictory views of the system and its operation, there is consensus that the program has an “overwhelming level of diversity and complexity.” Lofty in its goals but often miserly in its effects, Medicaid mirrors changing economic circumstances, conflicting political pressures, and fluctuating demographic and medical needs. The complicated partnership between states and the federal government has yielded more than 50 different programs, each with its own distinctive features and idiosyncrasies. Indeed, state variation in eligibility, covered care, program administration and reimbursement for services is

now the rule rather than the exception.

### A Labored Birth

Medicaid was a political stepchild from its birth. In 1965, the “first order of business” was the passage of Medicare, a high-profile bill that promised medical insurance for the 65+ population. Indeed, the legislation providing health insurance for the aged became H.R. 1 and Senate 1, its number symbol signifying its priority among President Lyndon B. Johnson’s Great Society initiatives. In the political arena, however, the bill underwent numerous modifications, including the incorporation of Title 19 (now known as Medicaid) as

an add-on covering the poor. In the hoopla surrounding passage of the bill, it was the enactment of Medicare that garnered all the publicity. While Medicaid had the potential of covering a larger population, it was almost a footnote in the struggle for greater access to care. Additionally, even its chief architects and advocates saw it as a mere steppingstone to a comprehensive national health care scheme that would ultimately supersede the legislation of 1965.

### Current coverage

Not surprisingly, Medicaid is the subject of new debate and rethinking.

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## MEDICAID, from page 1

In 2005, Mike Leavitt, Secretary of the US Department of Health and Human Services, declared that the program was no longer meeting its potential, and appointed a commission to plan for an improved Medicaid that would "provide quality care in a financially sustainable way." The commission presented two reports with recommendation framed so broadly, in the words of policy analysts at the Center on Budget and Policy Priorities, that "it is difficult to determine exactly what policy changes they would make." Additionally, given the changed Congressional climate and competing national and international issues currently on the agenda, it is impossible to predict any concerted focus on Medicaid in the next year.

Yet Medicaid affects the lives of tens of millions of Americans, commands an increasing share of the health care budget at the federal and state levels, and probably lends itself to more interventions than any other health program. Time and again, the program has served as a platform from which to address a number of health-related issues, be these emerging disease entities (e.g., HIV/AIDS), the delivery of new medical tools (cancer screening), expanding modalities of care (e.g., managed care), or the inclusion of vulnerable populations (e.g., those displaced by Hurricane Katrina).

Although Medicare gets more press coverage and political attention at the national level, Medicaid is the larger, more complex, and more politically fraught program. In terms of sheer

numbers, the impact of Medicaid is impressive: at present, Medicaid:

- covers more than 57 million Americans,
- insures one out of every four children,
- pays for more than one-third of all births,
- covers 60 percent of persons residing in nursing homes, and
- accounts for one out of every six dollars spent on health care in the United States today.

### Medicaid's Fiscal Complexity

Medicaid's complex funding formula is based on a partnership between the states and the federal government. Federal funding for the program comes from general revenues. As an entitlement program, Medicaid has spending levels that are pegged to the number of people participating in the program and the services provided. Spending is therefore open-ended and subject to fluctuations which are difficult to budget. As costs have risen over time, the program has become an important arena in which issues related to resource allocation have played out.

Even when states may be reluctant to commit an increasing share of their revenues to the program, the political and economic reality is that they need to leverage their share of the costs to maximize what they get from the federal program. As Urban Institute policy analyst Alan Weil has indicated, Medicaid's financing mechanism is inherently expansionary. The federal

government can expand coverage, knowing that it will pay only somewhat more than half the cost, the states picking up the balance. And the states can take advantage of federal incentives to provide broader benefits or cover a wider population, benefiting their constituents while their taxpayers pay only a fraction of total costs. This situation, which has been called a "minuet of mutual deception" between the two layers of government, is partly responsible for the continuing expansion of the program. It is therefore not surprising that the stakes are high for all participants in the program.

### Measuring Up

Twenty years ago, Public Citizen's Health Research Group did a state-by-state assessment of the Medicaid program. That report ranked all states on the basis of five criteria: eligibility, services, provider availability, quality, and reimbursement. Each of these was measured through an array of operational indicators. Public Citizen's 1987 report was used by states to examine their status vis-à-vis other states and the nation as a whole. The report prompted states to confront their deficiencies and improve their programs. It also provided ammunition to those states that were getting less than their fair share in federal funds or had not fared well in the monies allocated by their state legislatures. In addition, the report underscored the disparities that existed among states, thereby revealing the significant differences in access to care that Americans face simply because of

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THE PUBLIC CITIZEN HEALTH RESEARCH GROUP

## Health Letter

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# Work and Wellness: Collusion or Collision?

**H**ealth is not only a worthy end, but also a valuable means: health enhances life, facilitates liberty, and makes possible the pursuit of happiness. But not everyone assigns health the same value. Faced with behaviors that are pleasant but unhealthful, or unpleasant but healthful, many choose pleasure over health. The choice is often distorted because the results of one or another choice are felt over different time spans: a

pleasure payoff tends to be immediate, while a health effect usually takes time. Moreover, healthful behaviors often have a "threshold" effect: only after a particular behavior has been sustained over time is its positive impact likely to show. It is therefore not surprising that, when the cost-benefit equation takes the time dimension into account, health is often sacrificed to other goals.

As third-party payment has become

the norm in U.S. medical care, health has become everyone's business. Because states are at least partially responsible for Medicaid expenditures, they have a vested interest in protecting and promoting the health of their beneficiaries. Similarly, employers who provide insurance coverage for their employees will enhance their profits and productivity if their insurance bill is kept in check by workers who accrue

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## **MEDICAID, from page 2**

where they happen to live.

Public Citizen's Health Research Group is currently taking another look at the states' Medicaid programs, and will publish its results next month. An update is particularly timely and necessary because many changes have taken place over the course of two decades. Much federal legislation has either focused on Medicaid or enacted changes in health and welfare services that have had important implications for Medicaid. These changes have affected each of the criteria that we focused on in the previous report, as well as many of the indicators that were used to measure them. Furthermore, Medicaid has come of age. As the program enters its fifth decade, it is going through a programmatic 'midlife crisis'. It is therefore not surprising that Medicaid's advocates as well as its critics are taking stock of where the program is at present in order to point out areas where changes are needed. Although much of the concern revolves around program costs, we feel that this focus fails to address more fundamental aspects of the program, including equity in access to care and the quality of services rendered.

Using more than 100 indicators to score each state's program, the report addresses the scope of the program, its access to those in need and its monitoring of the services delivered. Like its 1987 predecessor, the report tries to answer the question: "If I were a poor, sick person, in which state would I

have the best chance of becoming eligible for Medicaid and getting comprehensive, quality health care?" The evaluation criteria used and the indicators used to measure them therefore reflect the consumers' perspective and aim to answer the following questions:

### **1. Am I eligible to receive Medicaid services in this state?**

Given the variety of pathways to determine eligibility, this is not an easy question to answer. An extensive list of requirements may enter the decision. Criteria for eligibility include the following: age, income, citizenship status, assets, work status, marital status, enrollment in school, medical condition, and improvement potential, among others. The permutations and combinations of eligibility requirements make for a complicated patchwork of enrollees. As a result, a "protected" population in one state may very well be expendable in another.

### **2. If I am eligible, does this state cover the particular services I need?**

While there are certain services that all states cover, there are more than 30 optional services that may be included in a state's offerings. And some of these may be covered only when given by certain providers; have limitations in terms of populations covered, frequency, duration, and scope; require cost-sharing; or may be provided only under certain conditions.

### **3. If the services are covered, will**

### **they be of adequate quality?**

Although Medicaid programs generate an inordinate number of statistics, and information technology has greatly facilitated the collection and analysis of data, most states lack measurable criteria to assess the quality of care they provide, or even to establish profiles of who is getting what care, when, and at what cost. Instead, the focus has been on billing and fraud detection. As a result, data on quality are very spotty.

### **4. Will the state pay for my services in a way that encourages access, equity and quality?**

States have been experimenting with ways to expand their coverage while keeping costs down and increasing efficiency. In some cases, these objectives are at cross-purposes, and involve trade-offs that are not always explicit to the consumer. As more and more states have been granted waivers from the originally mandated services, they have been given greater leeway in coverage, reimbursement policies, and organization of services. An increasing proportion of Medicaid beneficiaries are now enrolled in managed care. And more states are experimenting with cost-sharing, ostensibly as a way of making consumers more "prudent purchasers" of health care.

The next issue of *Health Letter* will include the major findings of our most recent assessment and the state-by-state rankings of Medicaid programs throughout the country. ■

**WORK AND WELLNESS**, from page 3  
unused sick leave, stay out of hospitals and avoid long-term care. Those who are part of any risk pool also benefit from the good health of the other members in their pool: high users of services generate expenses that are ultimately shared by all. In sum, when it comes to health care, we have all become our "brothers' keepers."

It is therefore not surprising that payers of all sorts are actively engaged in finding ways to thwart noxious practices and promote health-enhancing behaviors. Businesses are embarking on wellness programs, defined as "an organized set of activities designed to help individuals and their family members make and/or maintain voluntary behavior changes that help them reduce their health risks and enhance their ability to function." These work-based programs provide incentives for employees to adopt good health habits and discontinue perilous ones. Concerned with rising health costs, more than 80 percent of businesses with 50 or more employees have adopted some sort of health promotion program. Some workplaces have redesigned their environments or instituted passive measures to get their employees to do the "right" thing. They therefore ban smoking, provide exercise rooms, sponsor on-site flu shots, and include more nutritious offerings in their cafeterias. Still other employers have introduced more active methods to change staff behaviors. These include paying for fitness and smoking-cessation programs, giving bonuses for weight loss, providing time off for exercise, and instituting health appraisals that assess the health status of their employees. In some cases, these appraisals are followed by counseling and guidance concerning behavior modification.

While wellness programs may be seen as a job "perk," not everyone welcomes disclosing health-related information to their employers; many resent their employers' intrusion in personal health decisions. Fearing that information on their health status may influence others' perceptions of their work performance and curtail their possibility for advancement,

they want to create a firewall between their health and their work. They argue that lifestyle should be kept separate from the workplace and that having third parties intrude in what and how they eat, drink, move, and spend their leisure time is an affront to personal privacy.

Opponents also present a second, more subtle objection: some employees object to competing with their colleagues on non-job-related terrain, and don't want to invite comparisons in areas that have nothing to do with job performance. This is the main objection to "healthy lifestyle contests" that focus on both individual and collective goals. In addition, the more self-conscious may simply not want their colleagues to see them struggling with weight loss, sweating on a treadmill, or failing at chin-ups. And doing yoga with the boss is practically no one's idea of fun. Thus, for every person who finds working out with their co-workers motivational and fun, there is someone who sees it as coercive and uncomfortable.

Another sensitive area concerns fairness in the distribution of incentives, especially when these incentives are monetary. Employers who offer dollar bonuses to those who quit smoking or achieve given weight goals are in effect discriminating against non-smokers and those whose weight falls within the desirable norm. Moreover, there is a question of sustainability: what happens if the pounds creep up, or smokers resume their habit? The alternative, rewarding participation rather than results so that all enrollees emerge as "winners," raises issues concerning monitoring of participation. It may also be unfair to those who do not need to participate because they have already adopted healthful practices.

This does not mean that employers cannot be supportive of their employees' health concerns, or that incentives cannot be designed to foster healthful practices without intruding into personal decisions. There are examples of programs that have met employees needs for privacy, allow for individual customization by providing different pathways to achieve a given objective, are equi-

table in the distribution of rewards, and do not allow the system to be "gamed." One such incentive-based program is designed to reward employees who meet or achieve eight out of 10 wellness criteria during the program years. As objectives have changed, criteria have been adjusted over time. Nevertheless, over the years they have included the following:

1. Three out of four calendar quarters without an unscheduled leave day
2. Completion of a "Health Risk Appraisal"
3. Attendance of "Wellness at Work" educational session
4. No lost time due to injury
5. Minimum of X points from participation in a fitness program
6. Declaration of seat belt use at all times when in a vehicle
7. Blood pressure below 140/90 mm/HG at four quarterly measurements during the year
8. Participation in nine or more wellness program activities
9. No tobacco use in the last three months
10. Less than \$250 of personal health claims costs (excluding preventive care)

Those who meet the challenge receive a monetary wellness bonus that increases each successive year. Those who participate in the program but do not meet the eight criteria receive a token reward to encourage participation. The program thus gives everyone an incentive to engage in its activities, rewards both efforts and outcomes, and allows persons to choose how they can best invest their time in meeting both their personal and their employers' goals. Over time, this program has proved its worth, enhancing employee health while yielding significant savings in increased productivity and lower health care costs. Indeed, a dollar invested in the program has resulted in a savings of \$7, an impressive cost-effectiveness ratio by any standard. ■



## A Note from the Editor:

# FDA Should Not Seek More Drug Company Money, Should Get All Funding From U.S. Treasury

*Statement of Dr. Sidney M. Wolfe,  
Director of Public Citizen's Health  
Research Group*

The Food and Drug Administration (FDA) is proposing that the Prescription Drug User Fee Act (PDUFA) be reauthorized by Congress this year and that under the act, drug companies give the agency nearly \$400 million a year. The FDA's crucial drug regulatory functions

are too important to be tainted and compromised by direct funding from the very companies whose drugs the agency reviews for safety.

All the better ideas that have been discussed for improving FDA functions of reviewing new drugs, post-market safety studies and advertising should be included in the agency's upcoming budget proposal to the congressional appropriations committees. The agency should request these additional

funds through the same process that funded the agency from 1906 through 1992—that is, the money should come from the federal Treasury, not the pharmaceutical industry.

Ironically, the entire annual amount of funds now sought from industry under PDUFA is equivalent to fewer than two days of the current expenditures for the disastrous war in Iraq. Where are the congressional priorities? ■

## Conflicts of Interest: An Issue That Will Not Go Away

*Last month in Health Letter, we discussed conflicts of interest in science and medicine that manifest themselves in the most fundamental sources of scientific knowledge. We described evidence of such conflicts in the gatekeepers of medical knowledge: the National Institutes of Health (NIH), institutional review boards, and major medical journals. This month, we continue with a different twist on the same theme.*

“I’m sure that the pen I have in my pocket has an ad for one of the big drug companies, but I don’t know or care what it says and that would never influence my prescribing,” said my physician when I told him that I worked for Public Citizen. I replied that, while he was speaking only for himself, the drug companies have done their research and have confirmed that their advertising campaigns and ‘freebies’ do pay off. Moreover, name recognition is all-important in any purchase. Given a choice between an unknown drug and one that is heavily advertised, physicians are more likely to go with the one they know. It is not coincidental that mentions of “the name you know, the brand you trust” are

recurring motifs in much contemporary advertising.

Recent data confirm that drug manufacturers are also savvy marketers, and that they consider physicians to be a prime target. In 2004 drug companies spent a total of \$7.8 billion influencing physicians. This computes to an aver-

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age of \$10,000 for every practicing doctor in the United States. If these companies gave each doctor a check

for this amount, we would be duly outraged. But the monies are doled out in dribbles, and take a variety of pathways, shapes, and venues: they include gifts, consulting contracts, meals, sponsorship of trips and professional conferences, and advertising in medical journals.

Moreover, the companies appear to have adopted the concept of “give early, give often” as their motto. Physicians-in-training are wooed and courted in both subtle and obvious ways. Some receive outright fellowships, or take advantage of research opportunities offered by the companies. Last year, some drug companies paid professional organization dues for doctors finishing their residencies and invited graduating medical students to lavish meals, thereby establishing a pattern to win and cement the young physicians’ allegiance. And, while all self-respecting doctors will argue that they will not sell their soul for a steak dinner, the acceptance of such gifts will establish a relationship that can only compromise their independent judgment in future prescribing.

Some academic medical centers, increasingly aware that the physicians  
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# Product Recalls

December 16, 2006 — January 19, 2007

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](http://www.fda.gov). Visit [www.recalls.gov](http://www.recalls.gov) for information about FDA recalls and recalls issued by other government agencies.

### 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

**FERO-FOLIC -500 Filmtab Tablets** (Controlled Release Iron with Vitamin C and Folic Acid), 30 Filmtab Tablets, Rx only; Current Good Manufacturing Practices (cGMP) Deviations. Lot #s 08-173-AA-2, exp. date: 10/01/2006; 08-173-AA-22, exp. date: 10/01/2006; 15-829-AA-21, exp. date: 05/01/2007; Abbott Pharmaceuticals PR Ltd.

**Levothroid** (levothyroxine sodium tablets, USP), 25 mcg, packaged in 100 and 1,000-tablet bottles, RX; Subpotent (9-month stability). Lot #: 010648 (100-tab.) and Lot #: 010652 (1,000-tab.), exp. date: 01/2007, Lloyd Inc.

**Pink Eye Relief Drops**, Homeopathic Remedy; select brand, Distributed By: Select Brand Distributors; Eckerd, Distributed by: Eckerd Corporation d/b/a/ Eckerd Pharmacy; Brooks, Distributed By: Maxi Drug Inc., d/b/a Brooks Pharmacy; Premier Value, Distributed By

Chain Drug Consortium, LLC; Equaline, Distributed by Albertsons, Inc.; Lack of assurance of sterility; not manufactured in accordance with current Good Manufacturing Practices Regulations. Lot #s: 150117, 150215, 151215, 151014, 1510141, 151102, 151105, 151106, 151110, 1511101, 1511102, 151204, 151212, 1512121, 1512123, 160101, 1601011, 160112, 160212; Pharmaceuticals, Inc.

**Ranitidine HCl Tablets**, USP 150 mg packaged in a blister card of 30 tablets; Failed Impurity Specification. Lot #: 602570, Wockhardt USA, Inc.

**Thyro-Tab** 0.025 mg, packaged in 150,000-tablet bulk drums intended for repackaging, RX; Subpotent (9-month stability). Lot #: HA35305, exp. date: 01/2007, Lloyd Inc.

#### CONFLICTS OF INTEREST, from page 5

they train model their professional behavior on that of their mentors and peers, have adopted new rules to limit the contact between researchers and practitioners, on the one hand, and pharmaceutical representatives, on the other. Yale and the University of Pennsylvania were the first to institute clear policy guidelines to stem potential conflicts of interests. More recently and with greater fanfare, Stanford Medical Center has followed suit. Following a series of press exposés revealing that the more than 700

members of the medical faculty reported 299 potential conflicts of interest related to their research and that more than one-third of the medical school's administrators and department chairs also acknowledged having outside research-related financial interests within the past four years, Stanford University adopted a "no pens or pizza" policy that is being criticized as both too strict (because of its ban on inexpensive trinkets) and not strict enough (because it allows faculty members to serve on corporate boards of companies that do business with the institution).

Those who feel that the no-freebies policy is too strict need to hear the words of bioethicist Arthur Caplan. Small gifts, he writes, are the most powerful. They catch recipients unaware, whereas big gifts raise physicians' conflict-sensing antennae. Supporting this, Stanford Medical School Dean Phillip Pizzo cites the example of Lyndon B. Johnson. Ever the consummate politician, Johnson gave voters toothbrushes with his name on them because he "wanted people to think about him morning and night." ■



## 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](http://www.cpsc.gov). Visit [www.recalls.gov](http://www.recalls.gov) for information about FDA recalls and recalls issued by other government agencies.

### *Name of Product; Problem; Manufacturer and Contact Information*

**Air Pumps.** Inflator Air Pumps can overheat and explode during use, posing a risk of lacerations to the user and nearby consumers. Sportsstuff Inc., (888) 814-8833 or [www.sportsstuff.com](http://www.sportsstuff.com).

**All-Terrain Vehicles.** On some of the Kawasaki 2007 model year KFX®50 and KFX®90 ATVs, the handlebar holder, tie-rod adjustment, and tie-rod end nuts may not have been tightened to the proper torque. Operation of the vehicle can cause the nuts to loosen, resulting in a loss of steering control. This poses a crash hazard, which can result in injury or death. Kawasaki Motors Corp., (866) 802-9381 or [www.kawasaki.com](http://www.kawasaki.com).

**Baby Feeding Spoons.** After extended use, the soft plastic tip on the BABYBJÖRN® Feeding Spoons can loosen and break off, posing a choking hazard to young children. BabySwede LLC, (866) 424-0200 or [www.babyswede.com](http://www.babyswede.com).

**Baby Rattles.** Small parts on the Plush Baby Rattles can break or detach, posing a choking hazard to young children. Additionally, the rattles' plastic ring can break and expose sharp points. Target, (800) 440-0680 or [www.Target.com](http://www.Target.com).

**Candle Holders.** Pumpkin-Shaped Candle Holders can crack, break or shatter when used with the tea light candles that accompany them, yielding sharp pieces of glass that pose a laceration hazard. QVC Inc., (800) 367-9444 or [www.qvc.com](http://www.qvc.com).

**Children's Hooded Sweatshirts.** Children's Hooded 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. Seena International, (866) 927-5596 or [www.brooklynxpress.com](http://www.brooklynxpress.com).

**Children's Necklaces.** The pendant on Children's Butterfly Necklaces contains high levels of lead. Lead is toxic if ingested by young children and can cause adverse health effects. U.S. Toy Co. Inc., (800) 832-0224 or [www.ustoy.com](http://www.ustoy.com).

**Children's Overalls.** The coatings on the snaps in Starting Out Shirt and Overalls contain excessive amounts of lead, posing a serious risk of lead poisoning and adverse health effects to young children. Samara Brothers LLC, (800) 985-9975, e-mail [info@samararecall.com](mailto:info@samararecall.com) or [www.samararecall.com](http://www.samararecall.com).

**Christmas Mug Gift Sets.** The buttons could detach from the plush characters sold with the Holiday Time™ Christmas Mug Gift Sets, posing a choking hazard to young children. Wal-Mart Stores Inc., (800) 925-6278 or [www.walmartstores.com](http://www.walmartstores.com).

**Cordless Saws.** The switch on DEWALT DC305 Model Reciprocating Saws can short circuit, posing a fire hazard. DEWALT Industrial Tool Co., (866) 751-9562 or [www.DEWALT.com](http://www.DEWALT.com).

**Cut-Out Tools.** The cord wire in DEWALT Model DW660 Cut-Out Tools could be damaged internally, posing a shock hazard to consumers. DEWALT Industrial Tool Co., (888) 263-9051 or [www.DEWALT.com](http://www.DEWALT.com).

**Frame Ornaments.** Small parts on the Photo Frame Ornaments can break or detach, posing a choking hazard to young children. Target, (800) 440-0680 or [www.Target.com](http://www.Target.com).

**Fruit Slicer and Corer.** The metal blade can separate from the Farberware® Classic Series™ Fruit Slicer and Corer's plastic handle during use, resulting in cuts to consumer's hands and fingers. Lifetime Brands Inc., (888) 568-1533 or [fruitslicer@lifetimebrands.com](mailto:fruitslicer@lifetimebrands.com).

**Gas Boilers.** Bermuda BSI and Cayman CWI Series Gas Boilers can generate excessive levels of carbon monoxide (CO) in the flue gases, posing a risk of CO poisoning. Crown Boiler Co., (877) 597-3321 or [www.crownboiler.com](http://www.crownboiler.com).

**Gemstone Ring Party Favors.** The Gigantic Gemstone Rings could contain high levels of lead. Lead is toxic if ingested by young children and can cause adverse health effects. Celebrate Express Inc., (888) 551-3995 or [www.celebrateexpress.com](http://www.celebrateexpress.com).

**Highchairs.** The Graco® Contempo™ Highchairs can collapse if it is not fully opened and locked into place from the storage position prior to use. If the highchair collapses, a child occupying the highchair can be injured. Graco Children's Products Inc., (877) 445-1312 or [www.gracobaby.com](http://www.gracobaby.com).

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# Conflicts of Interest Among Clinical Investigators

*The following article appeared in the November 1993 edition of Health Letter. The topic remains as relevant today as it was over 13 years ago because there has been no progress made on this issue.*

Imagine the following: You are involved in a lawsuit against a manufacturer whose product you say caused you injury. During the trial, you get the impression that the judge is favoring your opponent — ruling to his or her advantage on

motions, objections, evidence and the like, and you end up losing. Later, you learn that the judge had a significant financial interest — stocks and stock options — in the company you sued. Would you suspect that you had been had by a biased judge? You bet! And would you be justified in appealing on grounds of conflict of interest? Again, yes; judges in this situation have a duty to disclose any interest and to remove themselves from the case.

So, what about doctors who act as

clinical investigators, testing drugs for pharmaceutical companies? Are they also required by law or custom to disclose financial interest in the companies sponsoring their work? No way! There is no law or regulation preventing a clinical investigator from holding stock, stock options, patents, licenses or any other financial interest in the company that makes the drug or product he or she is testing. And the Food and Drug Administration (FDA), which oversees drug trials, does not

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## CONSUMER PRODUCTS *cont.*

### *Name of Product; Problem; Manufacturer and Contact Information*

**Magnetic Construction Toys.** Tiny magnets inside the building pieces of the MagneBlocks™ Magnetic Construction Toys can fall out. Magnets found by young children can be swallowed or aspirated. If more than one magnet is swallowed, the magnets can attract each other and cause intestinal perforation or blockage, which can be fatal. Geometix International LLC, (866) 775-0265 or [www.magneblocks.com](http://www.magneblocks.com).

**NOS Kit Bottles.** An incorrect burst disc, a component of the NOS bottle valve, may have been installed in the NOS Kits for Snowmobiles and ATVs. If the bottle is overfilled and overheated, it could forcefully burst, posing an impact injury hazard to consumers. Nitrous Oxide Systems, (800) 638-0032.

**Pool Heaters.** MiniMax® NT STD Gas Pool Heaters can emit excessive carbon monoxide (CO), posing a risk of CO poisoning in the event of a vent leak in an indoor installation. Water Pool and Spa Inc., (866)-761-5272 or [www.pentairpool.com](http://www.pentairpool.com).

**Portable Generators.** A ground fault circuit interrupter (GFCI) installed on DEWALT DG2900 Portable Generators could fail to operate properly, posing a risk of electric shock to consumers. DEWALT Industrial Tool Co., (888) 742-9108 or [www.DEWALT.com](http://www.DEWALT.com).

**Remote Control Toy Helicopters.** The Remote-Control Dragonfly King HX-242 Helicopter (also known as the Micro R/C Helicopter) battery can overheat and catch fire, posing a burn hazard to consumers. ThinkGeek Inc., (888) 433-5788 or email [recall@thinkgeek.com](mailto:recall@thinkgeek.com).

**Road Bikes.** The Cannondale 2007 Model Road Bicycle's front brake can fail, causing the rider to lose control and fall. Cannondale Bicycle Corp., (800) BIKE-USA or [www.cannondale.com](http://www.cannondale.com).

**Space Heaters.** Oscillating Ceramic Heaters can overheat and smoke, which could pose a fire hazard to consumers. Family Dollar Stores, (800) 547-0359 or [www.familydollar.com](http://www.familydollar.com).

**Strollers.** Children can touch the rear tires when in the add-on seat of the Phil & Teds e3 Strollers with doubles seats. This can pose an abrasion hazard to children. Regal Lager Inc., (800) 593-5522, email [info@regallager.com](mailto:info@regallager.com) or [www.regallager.com](http://www.regallager.com).

**Teethers.** The flexible plastic ring that holds the Bright Starts Star Teether Beads and Bright Starts Teether Beads in place can crack or break, and the beads can detach, posing a choking hazard to infants. Kids II Inc., (877) 325-7056 or [www.kidsii.com](http://www.kidsii.com).

**Trim Assembly Kits.** Heat from the light bulb can cause the Trim Assembly Kits for Recessed Light Fixtures' plastic trim to soften and melt, causing the trim and lens to fall. This can result in laceration injuries to nearby consumers. Progress Lighting Inc., (877) 369-4548 or [www.progresslighting.com](http://www.progresslighting.com).

**Trim Assembly Kits.** Heat from the light bulb can cause the Trim Assembly Kits for Recessed Light Fixtures' plastic trim to soften and melt, causing the trim and lens to fall. This can result in laceration injuries to nearby consumers. Prescolite Inc., (866) 269-6318 or [www.prescolite.com](http://www.prescolite.com).



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even require that such arrangements be disclosed.

More than 34 years ago, Dr. Sidney Wolfe testified before a Senate hearing on clinical investigators' possible financial conflicts of interest.

What brought the issue to the Senate's attention was the clinical investigation of a soft contact lens. The doctors doing the trials were paid not in money (as is customary) but in stock and stock options. The investigators wrote optimistic reports about the lens' potential and the manufacturer's stock rose in response. Dr. Wolfe stated then:

How, under these circumstances, can objective scientific inquiry flourish? ... Why are practitioners now (compensated only by the patient, rather than by the patient and the company, as before) reporting what appears to be a larger number and greater variety of adverse reactions than did their doubly-compensated counterparts during the pre-market investigational stage? ... [A]s long as the manufacturers, medical schools and the FDA continue to condone such practices ... the American public will be the victims.

More than two decades later – on September 9, 1993 – the FDA convened its Science Board to address this long-standing question of financial disclosure by investigators in clinical trials. In attendance were speakers representing the academic and scientific communities, consumer organizations including Public Citizen's Health Research Group, manufacturers of drugs and medical devices, and the federal government. Public Citizen's responses to questions raised by the Board were as follows:

**1. Do financial interests of a clinical investigator in the product under study or the product sponsor have the potential to bias the outcome of studies undertaken by the sponsor?**

**Yes.** Investigators should not gain financially from companies whose products they are evaluating. For the FDA not to have a policy in this area is to invite investigator bias. An investiga-

tor may be unconsciously affected by an economic incentive, causing him or her to downplay negative data and exaggerate favorable data. A financial interest may affect the way research is carried out, analyzed or reported.

According to an article in the August 1993 *New England Journal of Medicine*, the basic purposes of conflict of interest rules are to maintain the objectivity of professional judgment and to maintain public confidence in professional judgment. In many areas of life, restrictions on conflicts of interest are the norm. For example, as previously mentioned, judges are expected to excuse themselves from cases in which they have an interest, not only to eliminate bias, but to eliminate the appearance of bias or partiality.

**2. Is the potential for bias in this area sufficient to warrant requiring disclosure of these interests to the FDA in some or all cases?**

**Yes.** Disclosure is warranted, but disclosure alone is not enough – it only announces that the risk of bias is present. Clinical researchers should disclose all financial arrangements as well as any ancillary ties to companies whose products they are investigating, such as educational activities supported by the companies, participation in other research projects funded by the companies, and consulting arrangements. Disclosure should be to the FDA, to the medical center where research is conducted, to organizations that are funding the research, and to journals that publish the results.

Furthermore, financial disclosures ought to be made to the FDA early in the review process. We believe that there is enough risk to subjects and data integrity during the early stages that financial disclosure ought to be made at that time.

Investigators ought to have to disclose information about themselves and family members, such as parents, children, and spouses.

**3. Do certain types of financial interest pose a greater potential for bias (e.g., equity interests or other forms of compensation where the value of interest/compensation may be influenced by the outcome of the study)?**

**Yes.** Researchers who might benefit financially by distorting their work have a conflict of interest even if they do not actually distort [it]. The circumstances determine whether there is a conflict of interest, not the outcome. Associations with business which could affect the outcome of a study include direct employment and consultancy, stock ownership, and patent-licensing agreements.

**4. Apart from outcome-dependent interests, are there interests that should be of special concern to the FDA (e.g., large retainer or consulting fees)?**

**Yes.** Of these, can a financial threshold be identified below which the FDA may reasonably assume that such financial interests are unlikely to have influenced the outcome of the study? It would be very difficult to set a safe threshold.

**5. If the FDA were to require disclosure of specified financial interests held by investigators, what steps should the FDA take to minimize the potential for bias resulting from such studies?**

**Disclosure alone is not enough.** Researchers with outcome-dependent interests should be banned from taking part in studies. Any other payment by the company, if allowed at all, should be commensurate with actual efforts expended on behalf of the company, and should be disclosed to the FDA. The FDA is already operating under an enormous statutory burden and should not be responsible for reducing the potential for bias resulting from financial interests.

**6. Are there forms of compensation or financial interests that create a significant enough risk of biasing a study to cause the FDA not to rely on the study?**

**Yes.** When the sponsor and the investigator are the same person, or are closely related (business partners), as is the case with many start-up device and drug companies.

**7. What could be the effects of such a determination on the development of drugs, biotech products and medical devices?**

It may delay the approval of some  
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drugs and devices, because the companies will be forced to repeat the studies.

**8. Are there methods of minimizing bias, e.g., blinding, independent assessments of study endpoints, participation of multiple investigators (most of whom have no financial interest) that are or could in some cases be adequate to protect against the potential for biases created by an investigator's financial interests? Should utilization of such methods be required (or shown not to be needed) whenever**

**an investigator holds and interest in the product or the sponsor?**

**No.** The FDA should not get involved in determining whether or not various methods employed by companies are adequate to sufficiently eliminate bias, or even whether such methods are needed. Rather, there should be a ban on such arrangements, and a disclosure requirement. It is safer and more responsible to decide in advance to remove factors that tend to distract researchers from concentrating on medical and scholarly goals.

**9. If the FDA were to require disclosure of specified financial interests,**

**should the FDA disclose these financial interests to the public? If so, what is the appropriate forum to release this information publicly?**

**Public disclosure of this information in some useful form is critical.**

The FDA cannot always do its job alone. It is imperative that the public be able to play some policing function in this area. Our organization, and others, often examine data submitted to the FDA and bring problems to the public's and agency's attention. Public disclosure is a positive good in itself, and it has a way of preventing substantive abuses in the first place. ■

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benefit the few with severe symptoms, one has to wonder about the effect on the many whose symptoms are mild, intermittent or transient.

The other source is the drive to find disease early. While diagnoses used to be reserved for serious illness, we now diagnose illness in people who have no symptoms at all, those with so-called predisease or those "at risk."

Two developments accelerate this process. First, advanced technology allows doctors to look really hard for things to be wrong. We can detect trace molecules in the blood. We can direct fiber-optic devices into every orifice. And CT scans, ultrasounds, M.R.I. and PET scans let doctors define subtle structural defects deep inside the body. These technologies make it possible to give a diagnosis to just about everybody: arthritis in people without joint pain, stomach damage in people without heartburn and prostate cancer in over a million people who, but for testing, would have lived as long without being a cancer patient.

Second, the rules are changing. Expert panels constantly expand what constitutes disease: thresholds for diagnosing diabetes, hypertension, osteoporosis and obesity have all fallen in the last few years. The criterion for normal cholesterol has dropped multiple times. With these changes, disease can now be diagnosed in more than half the population.

Most of us assume that all this additional diagnosis can only be beneficial. And some of it is. But at the extreme, the logic of early detection is absurd. If more than half of us are sick, what does it mean to be normal? Many more of us harbor "pre-disease" than will ever get disease, and all of us are "at risk." The medicalization of everyday life is no less problematic. Exactly what are we doing to our children when 40 percent of summer campers are on one or more chronic prescription medications?

No one should take the process of making people into patients lightly. There are real drawbacks. Simply labeling people as diseased can make them feel anxious and vulnerable – a particular concern in children.

But the real problem with the epidemic of diagnoses is that it leads to an epidemic of treatments. Not all treatments have important benefits, but almost all can have harms. Sometimes the harms are known, but often the harms of new therapies take years to emerge – after many have been exposed. For the severely ill, these harms generally pale relative to the potential benefits. But for those experiencing mild symptoms, the harms become much more relevant. And for the many labeled as having predisease or as being "at risk" but destined to remain healthy, treatment can only cause harm.

The epidemic of diagnoses has many causes. More diagnoses mean

more money for drug manufacturers, hospitals, physicians and disease advocacy groups. Researchers, and even the disease-based organization of the National Institutes of Health, secure their stature (and financing) by promoting the detection of "their" disease. Medico-legal concerns also drive the epidemic. While failing to make a diagnosis can result in lawsuits, there are no corresponding penalties for overdiagnosis. Thus, the path of least resistance for clinicians is to diagnose liberally – even when we wonder if doing so really helps our patients.

As more of us are being told we are sick, fewer of us are being told we are well. People need to think hard about the benefits and risks of increased diagnosis: the fundamental question they face is whether or not to become a patient. And doctors need to remember the value of reassuring people that they are not sick. Perhaps someone should start monitoring a new health metric: the proportion of the population not requiring medical care. And the National Institutes of Health could propose a new goal for medical researchers: reduce the need for medical services, not increase it. ■

*Dr. Welch is the author of "Should I Be Tested for Cancer? Maybe Not and Here's Why" (University of California Press). Dr. Schwartz and Dr. Woloshin are senior research associates at the VA Outcomes Group in White River Junction, Vt.*



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## Essay: What's Making Us Sick Is an Epidemic of Diagnoses

*This Article is by H. Gilbert Welch, Lisa Schwartz and Steven Woloshin.*

*The following essay appeared in the January 2, 2007, edition of The New York Times. We are republishing it with permission of the New York Times because it is a timely and important topic that we feel would be of interest to our readers.*

January 2, 2007

For most Americans, the biggest health threat is not avian flu, West Nile or mad cow disease. It's our health-care system.

You might think this is because doctors make mistakes (we do make mistakes). But you can't be a victim of medical error if you are not in the system. The larger threat posed by American medicine is that more and

more of us are being drawn into the system not because of an epidemic of disease, but because of an epidemic of diagnoses.

Americans live longer than ever, yet more of us are told we are sick.

How can this be? One reason is that we devote more resources to medical care than any other country. Some of this investment is productive, curing disease and alleviating suffering. But it also leads to more diagnoses, a trend that has become an epidemic.

This epidemic is a threat to your health. It has two distinct sources. One is the medicalization of everyday life. Most of us experience physical or emotional sensations we don't like,

and in the past, this was considered a part of life. Increasingly, however, such sensations are considered symptoms of disease. Everyday experiences like insomnia, sadness, twitchy legs and impaired sex drive now become diagnoses: sleep disorder, depression, restless leg syndrome and sexual dysfunction.

Perhaps most worrisome is the medicalization of childhood. If children cough after exercising, they have asthma; if they have trouble reading, they are dyslexic; if they are unhappy, they are depressed; and if they alternate between unhappiness and liveliness, they have bipolar disorder. While these diagnoses may

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