PUBLIC CITIZEN HEALTH RESEARCH GROUP

Health Letter

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Equal Pay for Equal Work? Not for Medicaid Doctors

How much physicians are paid, and what they are paid for, influences the amount and type of care they provide. Payments also have an effect on patient load. Generally, physicians have a "target income" which they aspire to reach. They will therefore adjust their services to reach this goal. As indicated in *Promoting Greater Efficiency in Medicare* (June 2007), the most recent Report to Congress of the Medicare Payment Advisory Commission:

> Overvalued services may be overprovided, because they are more profitable than other services. Under-valued services may prompt providers to increase volume to maintain their overall level of payment. Conversely, some providers may not furnish services that are undervalued, which can threaten beneficiaries' access to care.

An even more egregious impact occurs when it is entire segments of the population that are undervalued. When doctors earn different payments depending on whom they serve, they will tend to favor higher-paying patients, who will yield a higher fee for a given procedure. Moreover, physicians may decide to place a cap on the number of patients for whom they are paid less, thereby limiting access for these patients.

Unfortunately, payment differentials are embedded in policy, with different fees being paid for the same service under two publicly-financed programs: Medicaid, which seeks to serve the poor, and Medicare, which covers primarily the aged. Medicaid fees vary greatly from one state to another, with differences that cannot be explained on the basis of cost of living, practice expenses or any other factor.

Medicare fees are based on a relative value schedule and are established nationally, although they vary somewhat from one state to another. Fees incorporate a geographic adjustment factor (GAF) which takes into account variations in the costs of medical practice in different areas of the country. The GAF reflects geographic differences in three components known as Geographic Practice Cost Indexes (GPCIs or "gypsies" for short): physician's work, practice expenses, and malpractice insurance. The adoption of a fee schedule, even one that takes into account practice differences within and among states, has significantly reduced previous geographic differences in Medicare payments: while the difference in payment between the top- and bottom-paying states was many-fold before the adoption of a geographically-adjusted relative value scale, the difference between what the lowest-paying state and the highest-paying state paid for a given procedure was not more than 25-30 percent in 2002.

In contrast, Medicaid fees are established by each state. For the nation as a whole, Medicaid fees are lower than Medicare fees; the data for 2003 indicate that, overall, Medicaid paid $0.69 for every $1.00 paid by Medicare for the same set of services. But the Medicaid-to-Medicare ratio varies greatly from one state to another, with two states paying more under Medicaid, a few paying at or near parity with Medicare, but most paying their Medicaid providers significantly less than they earn under Medicare. There

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are also marked differences in the fees that different state Medicaid programs pay for the same procedures. As a result, some providers are not finding it financially viable to serve Medicaid patients.

Purpose and methods

In order to ascertain what Medicaid and Medicare providers earn for specific primary care-related services in given states, we computed the current (2007) Medicare fees for 10 states and the District of Columbia (DC), and compared them with the corresponding fees under Medicaid. We also examined inter-state differences in Medicaid program reimbursement in the same 10 states and DC, using their current fee schedules.

The selection of states we focused on was based on an Urban Institute study, which used 2003 data and was published in 2004. We focused on the states with the greatest fee parity (two were tied) and the states with the most significant disparities (Medicaid vs. Medicare) in their payments for primary care. In order to obtain the current (2007) Medicare payments, we computed the current fees for a basket of primary care services comprised of 11 procedures. These are the same procedures included in the prior study, although the data are not directly comparable because the 2004 study weighted the individual fees to reflect the relative importance of each service and each state.

Using the 2007 GPCIs and the relative value units for each component of the fee from the *Medicare RBRVS: The Physicians' Guide*, the fees for the chosen procedures were computed for each state. Three states – New York, Pennsylvania, New Jersey – had more than one Medicare payment area. In those cases, the formula was applied to each area and the average for each procedure was computed for the state as a whole. This yielded fees for the 11 primary care procedures under study in the 11 states. The sum of the fees for the individual procedures was the fee for the total primary care package.

The Medicaid data for each corresponding procedure were obtained from each state's Medicaid fee schedule. The fees for the 11 procedures were then added, and the totals for Medicaid and Medicare were then compared. This yielded the Medicaid-to-Medicare ratio for primary care services.

We also looked at the variation in Medicaid payments among states, focusing on the selected group of primary care services and how these are reimbursed in low-parity states in comparison with those that have high parity. Because the latter included two states that are statistical outliers, we omitted those states and computed the average Medicaid payments for the remaining four higher-paying states. It was these average payments that were compared to the state-specific fees for the low-paying states.

Table 1: Medicaid-to-Medicare Fee Ratios for Selected Primary Care Procedures, High-Parity States, 2007

State	2007
Alaska	1.38
Wyoming	1.25
Delaware	1.00
Arizona	.99
North Carolina	.92
Arkansas	.91

Table 2: Medicaid-to-Medicare Fee Ratios for Selected Primary Care Procedures, Low-Parity States, 2007

State	2007
New York	.29
New Jersey	.31
Rhode Island	.40
Pennsylvania	.42
District of Columbia	.48

Part A: Current Medicaid-to-Medicare ratios in 11 states

Tables 1 and 2 present some of the current Medicaid-to-Medicare ratios for a group of primary care services. The states that ranked at the top in 2003 now have the Medicare-to-Medicaid ratios listed in Table 1.

At present, Wyoming and Alaska emerge as statistical outliers, paying their Medicaid primary care providers significantly more than Medicare practitioners receive. That can be explained by their relatively sparse populations, and their need to recruit and retain practitioners. Delaware and Arizona continue as states that pay their Medicaid primary care providers equitably compared to their Medicare counterparts, followed by North Carolina and Arkansas. Delaware has in effect adopted the Medicare fee schedule for its Medicaid program, thereby paying providers the same regardless of the population served.

The states that had the lowest ratios and therefore had the highest disparities in Medicaid and Medicare payments in 2003 now have the Medicaid-to-Medicare ratios shown in Table 2.

New York and New Jersey clearly emerge as the states with the worse primary care Medicaid-to-Medicare ratios.

Part B: Actual reimbursement differences among states for Medicaid, and within states for Medicaid and Medicare

We also looked at what the state Medicaid programs in these same 10 states and DC pay for four primary care procedures or services. In each case, the states with the least parity are compared with the average fee for four of the high-parity states (omitting Alaska and Wyoming, which represent extreme values and would have distorted the comparison). These four states are referred to as the "high-paying states". The results are summarized in Table 3.

Geographical adjustments and the adoption of a relative value fee schedule have made Medicare payments more equal over time. At the same time, Medicaid payments have been left to state initiatives and have lagged behind, sometimes dramatically so. States with the highest disparities also have the lowest Medicaid fees overall. As indicated in Table 3, these states lag considerably in what they pay for primary procedures vis-à-vis the high-paying states.

While geography may not be

Table 3: Medicaid Fees for Selected Primary Care Procedures, Selected States, 2007

State	CPT #99213: Office visit, est pt, 15 mins	State Fee as % of HPS Fee	CPT #99244: Consultation, new or est pt, 60 mins	State Fee as % of HPS Fee	CPT # #93000: EKG	State Fee as % of HPS Fee	CPT # 92002: Ophth Serv, new pt	State Fee as % of HPS Fee
NY	$30.00	61%	$20.00	13%	$15.00	59%	$30.00	49%
NJ	$20.60	42%	$77.90	49%	$16.00	63%	$22.00	36%
RI	$20.64	42%	$49.00	31%	$16.31	64%	$30.89	50%
PA	$27.00	55%	$49.00	31%	$21.50	84%	$17.00	28%
DC	$27.11	55%	$86.98	55%	$16.00	63%	$50.00	82%
High-Paying States (HPS)*	$49.20	n/a	$157.92	n/a	$25.51	n/a	$61.32	n/a

* This represents the average for the four High-Paying States: Arizona, Arkansas, Delaware, and North Carolina.

Table 4: Medicare-to-Medicaid Fee Ratio for Specific Primary Care Procedures, Selected States, 2007

STATE	CPT #99213: Office visit, established patient, 15 minutes	CPT #99244: Consultation, new or established patient, 60 minutes	CPT #93000: Electrocardio gram (EKG)	CPT #92002: Ophthalmologic service, new patient
High-paying States (HPS)*	1.2	1.1	.91	1.1
NY	2.2	9.8	1.9	2.5
NJ	3.2	2.5	1.7	3.4
RI	2.9	3.7	1.5	2.2
PA	2.2	3.7	1.2	4.0
DC	2.5	2.3	1.8	1.6

* This represents the average for the four High-Paying States: Arizona, Arkansas, Delaware, and North Carolina.

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destiny, in the Medicaid program it can affect providers' incomes. It is therefore not surprising that the existing disparities have dissuaded many doctors from accepting Medicaid patients, and that Medicaid payments and their erosion over time has been a recurring source of friction between Medicaid practitioners and the state.

Clearly, practitioners in states such as New York, New Jersey, Rhode Island, Pennsylvania and DC are at a disadvantage compared to their counterparts in states such as Delaware and North Carolina. And, because these five disadvantaged jurisdictions include three populous states – New York, Pennsylvania and New Jersey – and account for more than 13.5 percent of all Medicaid beneficiaries, their failure to provide adequate payment affects a not insignificant fraction of physicians and enrollees. Moreover, because Medicaid fees have an effect on the capitated payments paid to managed care organizations under Medicaid, the depressed fee-for-service payments have a spillover effect on all Medicaid providers regardless of their reimbursement modality.

Table 4, which focuses on state-specific fees, shows the differences in what Medicaid and Medicare pay for given procedures within a same state. While the high-paying states have achieved near-parity with Medicare fees for the procedures under study (the Medicare-to-Medicaid ratios range from .91 to 1.2), providers in the five low-paying states earn significantly more for each service under Medicare than they do under Medicaid. The fact that practitioners providing the same service to two patients – one a Medicare beneficiary, the other a Medicaid patient – can earn from two to nine times more for the former, means that that practitioners have an economic incentive to favor one set of patients over the other, even when they have pledged to treat everyone equitably.

In general, the more time-consuming procedures show the greatest fee disparities. Thus, a one-hour consultation with a new or established patient (CPT Code 99244) is the most under-valued procedure in the five states, the Medicare payment being several-fold the Medicaid fee. The difference is particularly dramatic in some states, such as New York. The differences decrease somewhat when the patient-physician encounter is shorter, but they still range from two- to three-fold for an office visit with an established patient lasting 15 minutes (CPT Code 99213).

Differences in the fees paid by each of the two programs are less salient for procedures that are short and technology-dependent. Thus, the payments for an electrocardiogram (EKG; CPT Code 93000) are less disparate. Still, a physician in New York billing for an EKG will earn a fee that is 1.9 times higher under Medicare than under Medicaid.

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Similarly, providers in New Jersey and DC both earn 63 percent of what their Medicare counterparts earn for an EKG.

Price discrimination has therefore been not only allowed, but actually enshrined in the fee schedule that governs Medicaid, one of the nation's major health programs. That this is occurring under public auspices is unconscionable in a country in which many polls show that the vast majority of the population feels that everyone should have equal access to health care and that medical need rather than economic status should determine access to health care.

Implications

As long as Medicaid fee schedules short-change providers, the program and its clientele will be considered less worthy and access to care will be restricted for the poorest, neediest Americans. Fee differences between Medicare and Medicaid consign the Medicaid program to second-class status, and its beneficiaries to lower-tier care. Beyond the issue of disparate payments is the fact that many states pay too little; as a result, they have difficulty getting doctors to take Medicaid patients. This results in limited access to mainstream medical care for many.

The disparities among state Medicaid programs are equally worrisome. The existing differences are largely arbitrary, unrelated to population needs, physicians' competence, practice expenses, cost of living or any other reasonable explanatory factor. How then to account for the fact that an emergency department visit earns a fee three times as high in Delaware as it does in New York? And that a visit to an ophthalmologist in Pennsylvania is reimbursed at a rate that is less than one-third that paid to a similar practitioner in North Carolina? The fact is that what physicians are paid under Medicaid is the result of the accumulation of many decisions that are only tangentially related to equity for practitioners and greater access to patients.

Concerns related to low payments in the Medicaid program and fee disparities compared to Medicare are not new. As economist Rashi Fein has indicated, the differences, while shocking, "existed from the first days" of the programs. In 1991, a Federal advisory commission recommended that payments to doctors under Medicaid should be gradually increased to the amounts paid under Medicare. The major rationale for this was that increasing reimbursement would provide incentives for more physicians to care for poor people. A second reason given was that this would rationalize the payment of doctors under Medicaid by adopting a schedule that is calibrated to reflect the amount of work, overhead costs, and malpractice insurance costs associated with each service.

Although in 1991 the chair of the Ways and Means Subcommittee on Health introduced a bill that would require states to raise their Medicaid payment schedules to Medicare levels, this was never enacted. At the time, the cost of bringing the two programs to parity was estimated at $2.4 billion a year. It would be considerably more now, not only because of inflation but also because the programs currently provide a broader scope of services to more persons. In addition, services now are more technology-dependent; while in some cases technology may result in savings, more often than not it adds to the price of services. Moreover, the population has aged, thereby increasing the number and proportion of those most likely to consume more services.

In FY1991 Medicaid expenditures totaled $72 billion; by FY2005, this figure had reached more than $304 billion. Even a simple, linear extrapolation of the trend in Medicaid spending over the past 16 years means that achieving parity in payment would cost at least $10 billion per year. A fiscal impossibility? Not really. At present, the Pentagon is spending $6 billion per month waging war in Iraq. Reallocating a mere two months of the war budget would suffice to give Medicaid physicians parity with their Medicare counterparts for a full year. Fiscal impossibilities have a way of receding in the face of moral imperatives. It's all a matter of recommitting to health what we now so routinely commit to death. ■

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THE PUBLIC CITIZEN HEALTH RESEARCH GROUP
Health Letter

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Hoodia: The Latest in a String of Diet Pill Scams

The sea changed, the fields changed, the rivers, the villages, and the people changed, yet Egdon remained.

Thomas Hardy,
"The Return of the Native", 1878

* * *

When I was a little boy
And the Devil would call my name
I'd say "now who do . . .
Who do you think you're fooling?"

Paul Simon,
"She Loves me Like a Rock", 1973

As Thomas Hardy observed, some things never change. When the dietary supplement ephedra was finally yanked from the market in 2003, public health specialists breathed a sigh of relief. The product had been associated with more deaths than all other dietary supplements combined.

But where some saw belated success, others saw an opportunity for profiteering. No sooner was the product vanishing from supermarket shelves than new "ephedra-free" supplements appeared. The target: The 33 percent of Americans estimated in national surveys to be obese. Suddenly bitter orange, green tea and blue-green algae, previously low on the ladder of best-selling dietary supplements, became the rage. None has been proved effective.

If the colorfulness of the product doesn't suffice to spur product sales, there's always local color. One brand of noni juice, another unproven nostrum for obesity, is marketed as "an exotic health discovery from French Polynesia." Its label features a bare-chested local male with a mohawk haircut eating the fruit.

The newest diet phenom, hoodia gordonii, follows the same well-worn path. This time, the bare-chested man brandishing the hoodia-containing Desert Burn products is "Sean – A South African Bushman and Our Friend." (Memo to hoodia producers: The ethnographically correct term is San, not Bushman.) The Web site also depicts San traversing the desert in their loincloths, a scene reminiscent of the 1984 film "The Gods Must Be Crazy" – the last time the San penetrated US popular consciousness. Actually, most San wear western-style clothing, in some cases only donning loincloths when tourists and journalists visit them in their impoverished villages.

Another approach to product promotion: The endorsement of the impressionable scribe. In a 2004 report, Lesley Stahl of 60 Minutes testified that the product had suppressed her appetite, pronouncing the Southern African succulent "a little cucumbery in texture, but not bad." The BBC's Tom Mangold concurs: "We did not even think about food. Our brains really were telling us we were full. It was a magnificent deception."

Magnificent deception, indeed. There is not a shred of evidence in the medical literature that this product works in humans. Sure, a study has fingered some arcane impacts upon the brain in laboratory rats. In another study, 15 other lab rats appear to have kept their weight stable and a control group of six others piled on the milligrams. Although food consumption did drop while the rats were taking hoodia, five days later they were gulping down those delectable pellets just as voraciously as before the study began. That's a long way from easing you into those low-rise hip-huggers.

But, with today's discerning consumer, simply hyping a tablet with an unproven dietary supplement is not enough to boost market share. Hence, from Desert Burn Industries alone, one can purchase Hoodia Juice (in a dropper), Hoodia Shake, Hoodia Java and the ever-popular Hoodia Fruit Bar. The latest entrant into this crowded marketplace is the Hoodia Patch, allowing absorption of the product through the skin. We doubt the San took it this way.

Speaking of the San, the group has retained a lawyer who is trying to secure for the group a fraction of the international sales of hoodia-containing products. This is a reaction against bio-piracy in which corporate interests exploit chemicals used indigenously for centuries. "The San will finally throw off thousands of years of oppression, poverty, social isolation and discrimination," said the lawyer. "We will create trust funds with the hoodia royalties and the children will join South Africa's middle classes in our lifetime." Returns *for* the natives, Thomas Hardy might have suggested.

In addition to members of the legal profession, hoodia manufacturers have drawn the attention of regulators at the US Food and Drug Administration. Five hoodia manufacturers have received letters from the agency notifying them that their claims for the efficacy of their products have converted their products from dietary supplements into illegally marketed new drugs. Others have observed that the quantity of purportedly hoodia-containing product greatly exceeds that available in Southern Africa; the plant is considered endangered. The imbalance between supply and demand seems to have exerted itself in a predictable way: There are reports of products shown to contain no hoodia at all.

Hoodia is another in the long string of dietary supplement frauds perpetrated on the American public recently. Ever since dietary supplements were deregulated by the 1994 Dietary Supplement Health and Education Act, the market has been rife with products touting unproven cures, exploiting the legitimate health concerns of people with obesity, in particular. Due to this pernicious act, companies do not even have to prove that their products are safe. As Paul Simon might have asked, "Just hoodia think you're fooling?" ■

Product Recalls

August 24, 2007 — September 17, 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*. Visit *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

Cocaine: The Legal Alternative Energy Supplement; Unapproved New Drug; product's name and certain claims rendered the product an unapproved new drug. All lots; Gluek Brewing Co.

Cut Cocaine: The Legal Alternative Energy Supplement; Unapproved New Drug; product's name and certain claims rendered the product an unapproved new drug. All lots; Gluek Brewing Co.

Free Cocaine: The Legal Alternative Energy Supplement; Unapproved New Drug; product's name and certain claims rendered the product an unapproved new drug. All lots; Gluek Brewing Co.

Oral Bright Fresh Fluoride Toothpaste and Toothpaste/Toothbrush combo, Fresh Spearmint Flavor; Toothpaste from China may contain the poisonous chemical diethylene glycol (DEG). All lots; Goldcredit International Enterprises.

Springfresh Fluoride Toothpaste; Toothpaste from China may contain the poisonous chemical diethylene glycol (DEG). All lots; Suzhou Qing Xin Daily Chemical Co., Ltd.

Spearmint Fluoride Toothpaste; Toothpaste from China may contain the poisonous chemical diethylene glycol (DEG). All lots within expiry; Shanghai Whitecat Shareholding Co.

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 Product; Problem; Manufacturer and Contact Information

All-Terrain Vehicles. Ohalee FA-A70 Youth ATVs lack front brakes and a tire pressure gauge, the date of manufacture is not printed on side of the tires, and the front suspension is solid and does not allow for travel. Additionally, the flag pole bracket is not the correct size, and the handlebars do not have padding covering sharp edges. There is no storage location for the owner's manual, and the manual itself does not contain complete information on the safe operation and maintenance of the ATV. These defects could result in an unsafe riding condition, posing a risk of injury to young drivers. Ohalee Inc., (866) 867-5976 or www.ohalee.com.

Backpack Blowers. The outer shell of the Shindaiwa Backpack Blower's muffler can melt allowing exhaust gas to exit from the bottom or back side of the muffler. The exhaust gas may cause damage to the fuel tank creating a possible fire hazard for the user. Shindaiwa Inc., (800) 521-7733 or www.shindaiwa.com.

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Name of Product; Problem; Manufacturer and Contact Information

Bar Stools. The seat on ICE Bar Stools can detach, causing the consumer to fall and suffer injuries. Calligaris USA Inc., (336) 431-5500.

Bunk Beds. Jubee Bunk Beds do not comply with federal safety standards and have wooden side slat supports that can separate from the bed frame causing the upper bunk to collapse. d-Scan Inc., (800) 932-2006 or www.tvilum-scanbirk.com.

Children's Trailer Bicycles. Novara Afterburner Trailer Bicycles can detach from the adult bicycle, posing a fall hazard to children. Recreational Equipment Inc. (REI), (800) 426-4840 or www.rei.com.

Coloring Case. The printed ink on the outer packaging of the Imaginarium Wooden Coloring Cases contains lead. Also, some of the black watercolor paint contains excessive levels of lead, which violates the federal lead paint standard. Toys "R" Us Inc., (800) TOYSRUS/869-7787 or www.toysrus.com.

Convection Ovens. Wires behind the control panel of the Cook's Essentials Convection Ovens with Pull-Out Rotisserie and Deni Convection Ovens with Rotisserie can overheat, posing fire and electric shock hazards. QVC, (800) 336-4822 or www.qvc.com.

Cribs. The crib slats can separate from the side rails of "Moderne" and "Loft" Cribs, posing an entrapment and strangulation hazard to young children. NettoCollection LLC, (866) 996-3886 or www.nettocollection.com.

Electric Heaters. If the fan stops working and the heater continues to run, the unit can overheat, posing a fire hazard. Marley Engineered Products, (800) 642-4328 or www.berkomep.com/ts.htm.

Electric Heaters. The "Aloha Breeze" Portable Electric Heaters can overheat, posing a fire hazard. Aloha Housewares, Inc. (800) 295-4448 or ahitexaslg@aol.com.

Hats. Toddler and Youth Nylon Bucket Hats have a drawstring, posing a strangulation hazard to young children. Paramount Apparel International Inc., (866) 618-7179 or www.paramountapparel.com.

Iced Tea Makers. The IT400 Iced Tea Makers's components can fail, posing a fire hazard to consumers. Back to Basics Products LLC, (800) 874-4084 or www.backtobasicsproducts.com.

Logger Boots. The recalled Logger Boots could be incorrectly labeled as resistant to electrical current. This poses a shock hazard to consumers who come in contact with an electrical current. Wolverine World Wide Inc., (800) 789-8586 or www.wolverineworldwide.com.

Memory Chips. The memory chip in the Apex-Brand Destiny 6100 and 6100AN Security System Control Panels could lose programmed values in the event of a power outage exceeding four hours. If this occurs, the panel could fail to communicate with a central monitoring station and not sound an audible notification in the event of a fire or home intrusion. Honeywell International Inc., (800) 573-0154 or www.security.honeywell.com.

Outdoor Candles. The "Avant Yarde" Decorative Glaze Outdoor Candles' wax can catch fire causing a high flame, which poses a fire and burn hazard to consumers. The Hayes Company Inc., (800) 838-5053 or www.hayesco.com.

Pocket Knives. During use, the back of the blade of the Gerber EAB (Exchange-A-Blade) Pocket Knives can slide past the blade support, posing a laceration hazard to consumers. Gerber Legendary Blades, (877) 204-5510 or www.gerbergear.com.

Scuba Diving Gear. The AGA Swivels for Scuba Diving Masks, which is attached to a diving mask, could separate while diving. This will result in a sudden loss of the diver's air supply, causing the diver to engage in emergency ascent. This poses a risk of decompression sickness due to rapid ascent or drowning. M&J Engineering, (888) 794-8351 or www.mj-engineering.com.

Sweatshirts. Zippity Hoodie and Sherpa Full Zip 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. Life is Good Inc., (888) 339-2987 or Customer_Service@lifeisgood.com.

Tool Kits. Booster cables in the recalled Emergency Tool Kits can have undersized wiring and inadequate connections, posing a fire and shock hazard to consumers. B&F System Inc., (877) 586-2926 or www.bnfusa.com.

Torch Lamps. The head of Ceramic Oil Torch Lamps can come loose or be dislodged during use, allowing it to break and spill torch fuel. This poses a risk of cuts, fire or burn injuries and property damage. Wal-Mart Stores Inc., (800) 828-9316 or www.walmartstores.com.

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Research as Public Relations:
Antidepressants and Suicide in Youth

It seemed like déjà vu this September, as dramatic headlines again linked suicide and antidepressant use in youth. Three years ago, the weight of evidence seemed to point in the direction of increased suicide as a result of antidepressant use. In light of this, federal regulators at the Food and Drug Administration (FDA) required a "black box" label for all SSRI (selective serotonin reuptake inhibitor) antidepressants indicating that use in children could lead to an increased risk of suicidal behavior. Now comes a study published in the prestigious *American Journal of Psychiatry* (*Volume* 164, pp. 1356-1363) purporting to show, in effect, the opposite: the FDA warnings had caused the rate of pediatric SSRI prescriptions to plummet and as a result young people are killing themselves due to lack of treatment. If this were true, it would be a clear example of the unintended consequences of regulation.

But first, let's turn the clock back to the summer of 2003. The FDA had just warned doctors of an increased risk of suicidal thoughts and behavior in children on fluoxetine (Paxil). By October, the FDA publicly acknowledged that other antidepressants might have the same propensities and requested all unpublished data from SSRI makers, some of which had been hidden for years from the public. After discrediting the findings of Andrew Mosholder, its own drug-safety expert, the FDA commissioned a team from Columbia University to reassess the data. Almost a year later, the academic team came to the same conclusion as Mosholder: SSRI use in children and adolescents increased the risk of suicidal thoughts and behavior two-fold. After an emotional hearing in late 2004, the FDA issued a "black box" warning for all SSRIs for children, its strongest possible labeling change.

The *AJP* study addressed the interesting question of the impact of this regulatory action on the public health. Since then, said the study, the rate of SSRI prescriptions to children has declined, and Centers for Disease Control and Prevention (CDC) data showed a spike in youth suicides. Child psychologists lined up to inform readers that, overall, antidepressants were helpful for the majority of children, even if they hurt a few. But there is hardly a consensus on SSRI efficacy in children. Only one SSRI antidepressant, Prozac, is approved by the FDA for pediatric use. Experts including the lead author of the new study, Dr. Robert D. Gibbons, and the director of the National Institute of Mental Health (NIMH), Dr. Thomas Insel, blamed the FDA warnings for the subsequent drop in antidepressant prescribing to youth and the sudden rise in youth suicide. *The Washington Post* characterized their remarks as saying that the evidence "leaves few other plausible explanations."

Glossed over in this spate of stories was the evidence itself. The study simply juxtaposed two data sets over time: a 22 percent drop in the SSRI prescription rate in children 0 to 14 years old from 2003-2005 and a 14 percent increased rate of suicide in children aged 5 to 19 from 2003-2004. The first rate went down, and the second went up, observed the authors. Therefore, as Gibbons said, the study was part of a "very cohesive story" that suggested one had caused the other.

All studies are not created equal

Unfortunately, it's not quite that simple. There is a distinction in public health between data that are linked to specific individuals and those that only describe the population being studied. Relationships that can be demonstrated at the aggregate level may not be true at the individual level because it is impossible to track individual patients in such stud-

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CONSUMER PRODUCTS *cont.*

Name of Product; Problem; Manufacturer and Contact Information

Toy Bongos. Surface paints on the Big Big World 6-in-1 Bongo Band toys contain excessive levels of lead, which violates the federal law prohibiting lead paint on children's toys. Fisher-Price Inc., (888) 496-8330 or www.mattel.com/safety.

Toy Trains. Surface paints on the Geo Trax Locomotive Toys contain excessive levels of lead. Fisher-Price Inc., (888) 496-8330 or www.service.mattel.com.

Various Barbie Accessory Toys. Surface paints on Various Barbie Accessory Toys contain excessive levels of lead which is prohibited under federal law. Mattel Inc., (888) 496-8330 or www.mattel.com/safety.

Watering Cans. The beak of the Robbie Ducky™ Kids Watering Cans contains lead in the paint, which violates the federal law prohibiting lead paint on children's toys. Lead is toxic if ingested by young children and can cause adverse health effects. Jo-Ann Stores Inc., (888) 739-4120 ext. 7 or www.joann.com.

Weather Radios. Oregon Scientific Weather Radios could fail to receive National Weather Service alert signals in certain areas of the country. In the event of severe weather, this failure could put a consumer's life and property at risk. Oregon Scientific Inc., (800) 203-4921 or www2.oregonscientific.com.

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ies. For example, there is no way to know that the group who would have received antidepressants (in the absence of FDA warnings) was the same group that committed suicide. Conversely, the children who committed suicide could have been taking antidepressants at the time, even as fewer patients were being prescribed the drug. The coincidental movement of population-level SSRI prescription rates and suicide rates is also complicated by, among other things, demographic and socioeconomic factors, societal trends over time and individual differences in the various groups who received antidepressants.

While absolute certainty is rarely achievable even in human trials that randomly assign patients into treatment or control groups and then follow the individuals over time, such trials are vastly superior to the aggregate population rate approach. Considered the "gold standard" in the clinical trial field, randomized control trials (RCTs) are compelling because all factors that might complicate data interpretation should be equally distributed between the treatment and control groups as a result of randomization. Not surprisingly, therefore, the FDA chose to use a meta-analysis (a statistical combining of individual studies) of 24 RCTs as the basis for its warnings of increased suicidality in young SSRI users. It is highly unlikely that they would have relied on aggregate population data to make so far-reaching a label change.

Further, suicide has myriad interrelated causes and rates can vary substantially over the short-term. Isolation of a single factor to explain a population increase in suicide of 14 percent is hazardous unless the factor is overwhelmingly influential or only one variable at a time changes. The latter is the case in RCTs in that the only variable that is different between the treated and control groups at the beginning of the study is the treatment itself. Numerous studies based on dozens of published and unpublished RCTs have resulted in the FDA's conclusion that, of the SSRIs, only fluoxetine performs better than sugar pills for children under 18, although doctors can legally prescribe other SSRIs in children. Population-level studies have little to contribute, particularly when they are inconsistent with the well-designed RCTs. In short, the FDA's decisions were ultimately based upon much stronger evidence of the causal relationship between SSRI use and suicide than the *AJP* study.

Given these crippling methodological problems, one at least expects the numbers themselves to have been accurately presented. Sadly, even this was not the case. In fact, there was a decrease of only a few percentage points in SSRI prescription rates between 2003 and 2004, with the majority of the decrease occurring after that. Unfortunately, data on suicide were only available from the CDC through 2004. Thus the drop in prescription rates happened mostly after the demonstrated rise in suicides.

Even the age groups in the two data sources didn't coincide. The suicide rates were observed in children aged 5 to 19, but the widely quoted SSRI prescription rate drop of 22 percent applied only to children 0 to 10 years of age. The drop in SSRI prescription rates from 2003-5 was actually around 15 percent for children aged 10 to 14 and even less for teenagers 15 to 19 years old. The study does not report actual prescription numbers, but previous research shows significantly lower SSRI use in children younger than 10 years compared to 10 to 20 year olds. This suggests that the actual drop in the number of SSRIs to youth overall is considerably smaller than 22 percent.

In a highly unusual move that hinted at the presence of strong criticism, the *New York Times* wrote a counterpoint to its original story on this study two weeks after the paper was published. Entitled, "Experts question study on youth suicide rates," the article pointed out some of the study's methodological flaws that had eluded the *Times* in its initial article and emphasized the complexity of the debate.

The public health paradigm demands that decisions to prevent disease and promote health be made based on the best evidence available. Clearly, the latest "evidence" does not hold a candle to the meta-analysis of 24 randomized controlled studies that the FDA used to issue its original warnings. So why did this study gain so much attention?

Bad Faith

Prescribing antidepressants to youths had been increasing steadily since the 1980s, and accelerated further in the late 1990s, particularly for children. After the FDA warnings, the drop in SSRI prescribing for children represented an alarming fall in pharmaceutical industry revenue and a deviation from the expected meteoric rise in such prescribing. Clearly, it would be in the industry's interest to counter any perception that SSRIs were dangerous. Certainly, they had spared no effort in the past: heavily choreographed testimony before the FDA, to say nothing of the suppression of studies showing the drugs' dangers and ineffectiveness.

For two of the three industry-funded authors of the *AJP* study, the study's clear limitations seemed to offer few constraints. Dr. J. John Mann said, "The most plausible explanation is a cause and effect relationship: prescription rates change, therefore suicide rates change." Oddly, in the same article, Gibbons admitted that the data "did not support a causal link" but continued: "this study was suggestive, that's what we're saying." The six-page study itself barely spent more than a page on the data in question, and was instead devoted to the restatement of other population-based studies.

Viewed in this context, the paper and its subsequent publicity appear to be little more than a public relations ploy. The editors of the AJP should not have allowed such gross misrepresentations to pass into print unscathed, and journalists who cited this study as if it deserved equal credence to the RCTs are just as guilty.

Can't take the heat

Federal regulators were compelled to respond following the study's

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or healthcare workers. Numerous studies have shown that the use of infection surveillance and contact precautions can result in significant reductions in transmission rates.

An even more basic step taken by hospitals in these countries, as well as some in the US, is a renewed emphasis on basic hygiene. Thorough adherence by doctors and nurses to hand-washing protocols can greatly reduce the risk of infections spreading from patient to patient. Despite this information, compliance with hand hygiene standards in US hospitals system is estimated at only 40 to 50 percent. It is unclear how much of the responsibility for this lapse lies with the doctors and nurses themselves and how much is the result of hospitals not being set up to effectively support sanitation efforts.

According to infection control researcher Dr. Donald Goldmann, senior vice president of the Institute for Healthcare Improvement and professor at Harvard Medical School, systematic faults can range from lack of hygiene education and assessment to failure to maintain full soap dispensers. Dr. Goldmann proposes that hospitals take the steps necessary to allow and encourage their workers to follow proper hand hygiene practices. After that has been done doctors and nurses can be monitored and those found to be non-compliant held accountable.

This past July, the CDC released updated guidelines for infection prevention in healthcare settings that include key steps that have been proven to be effective. Precautions stressed include thorough hand and environmental hygiene, isolation of very contagious or susceptible patients and surface disinfection procedures. The guidelines are not mandatory, however, and many important measures have been recommended since 1996 without widespread compliance.

Some hospitals in the US have already started taking additional steps to protect their patients against the dangers of HAIs. Several healthcare consumer groups believe that this process will be expedited by required public reporting of hospital infection rates. Dr. Usha Stiefel, who is coordinating efforts to address HAIs at the Cleveland Veterans Affairs Hospital (VA), warns that these statistics are useful only when properly collected and interpreted. If done and utilized properly, however, many feel this type of published data could give patients the option of choosing a hospital that is taking the necessary precautions to ensure maximum patient well-being.

Laws requiring public reporting of hospital infection rates have already been passed in 14 states, including data by named hospital in some. Pennsylvania, New Jersey and Illinois have gone even further, and this year approved laws mandating routine pre-admission screening for infection in certain high-risk patients. These legislative mandates have been controversial, however, with members of the medical community on both sides of the issue. The presidents of the Society for Healthcare Epidemiology of America (SHEA) and Association of Professionals in Infection Control (APIC) have jointly stated that, while certain measures can be very effective, "infection prevention and control professionals need flexibility, autonomy, and authority to act as local conditions dictate...we do not need laws to mandate action."

Whether required to do so or not, implementing an aggressive infection prevention program may be in the hospital's best interest. The Pittsburg VA, which has served as a model of HAI control for the Cleveland VA branch as well as other hospitals around the country, realized $900,000 in net yearly savings after their program successfully cut the rate of infections.

Though the steps necessary in order to control the problem of HAIs seem to be available and accessible, it will likely be years before they have been fully implemented. In the meantime, it is advisable for patients to request that their doctors and nurses wash their hands or wear gloves before performing an examination. According to Dr. Stiefel, patients who are having elective surgeries that have a high risk of infection may also want to ask their healthcare providers if they should be screened and treated for drug-resistant bacteria prior to surgery. While these steps may be uncomfortable for some patients, asking medical professionals to follow what is standard safety protocol could prevent an unnecessary illness with potentially tragic consequences. ■

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widespread media coverage. Their responses afford little confidence that prominent regulators are any more able to identify overblown findings than their counterparts at the AJP or in the popular press. Dr. Insel of the NIMH said, "We may have inadvertently created a problem by putting a 'black box' warning on medications that were useful. If the drugs were doing more harm than good, then the reduction in prescription rates should mean the risk of suicide should go way down, and it hasn't gone down at all – it has gone up." Dr. Thomas Laughren, director of the Division of Psychiatry Products at the FDA, thought that more data over time "linking declines in prescriptions to suicide risk" would be enough cause for the FDA to revisit its black box labeling decision. While revision of regulatory warnings is sometimes necessary, to do so based upon studies like this would simply be capitulation to a pressure campaign.

While there is always room for debate on the effects and effectiveness of SSRIs in children, the debate has long since advanced past population-level studies like this one – let alone population-level studies with such egregious flaws and loaded with data misrepresentations. This study may be easy for press to understand, and its findings may be comforting for profit-minded drug companies and the physicians who have been prescribing these products, but that will be little consolation for the children who may receive these products as a result of the false reassurances doled out by this second-rate study. ■

Healthcare-Associated Infections: Are Hospitals Making Us Sicker?

In the early 20th century medical treatment advanced so that for the first time in history, a patient was generally better off seeking care from a doctor rather than avoiding formal medical treatment. Though in 2007 people admitted to hospitals have varying levels of optimism about the quality of care they will receive, few worry that during their stay they might acquire a serious or even deadly disease, separate from that which brought them to a hospital in the first place. Healthcare-associated infections (HAIs), however, are definitely a cause for concern.

HAIs are defined as infections that occur during a hospital stay and were not present on admission. This includes urinary tract infections, surgical site infections, pneumonia and other illnesses that can result when bacteria are acquired by a patient through contact with contaminated healthcare personnel or the hospital environment. The Federal Centers for Disease Control and Prevention (CDC) estimates that there are 1.7 million of these infections in the United States each year, resulting in 99,000 deaths. These startling figures, based on data from 2002, may actually underestimate a problem that has continued to worsen as bacteria spread and become increasingly resistant to treatment.

This is exemplified by the particularly troublesome pathogen Methicillin-Resistant Staphylococcus Aureus (MRSA). MRSA is often referred to as a "superbug" because it has acquired resistance to many common antibiotics including the penicillin derivative, methicillin. In the past 30 years, this bacterium has gone from causing 2 percent of all staph infections to more than 60 percent and is estimated to affect 4.6 percent of all in-patients in the US.

Though the risks posed by HAIs are serious, there are many who believe that simple and cost-effective solutions exist. In Finland and the Netherlands, the prevalence of MRSA has been maintained at a low level with adherence to rigorous transmission-based control policies. Among these preventive measures is a protocol for screening admitted patients for drug-resistant bacteria. MRSA carriers are treated for their infections and often placed in a separate area of the hospital where special care is taken to prevent transmission to other patients

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