PUBLIC CITIZEN HEALTH RESEARCH GROUP

Health Letter

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Q & A on the Current Health Debate

What does a 'public plan option' mean and why does Public Citizen oppose it?

As the health care debate enters the legislative stage and different measures are proposed, we will focus on some of the "hot buttons" that are under discussion. The idea of a "public plan option" is one of these. This column is devoted to questions and issues that our readers may have on this topic and to why we are opposed to it.

How is a 'public plan option' defined?

A "public plan option" is a government-operated insurance plan that would be offered to consumers as part of a scheme to provide universal coverage to the U.S. population. The plan is expected to compete against private insurance plans and is presented as coverage Americans can buy as an alternative to private insurance.

The plan has been described as similar to conventional Medicare; it would be managed by the federal government, which would pay private providers to deliver care. But there are different variations on this theme, with different eligibility requirements, scope of services, delivery systems, and payment modalities.

Whom would it cover?

Although presumably everyone would have a choice of plans, this option is aimed primarily at those under 65 years old who lack secure workplace insurance or who would want a plan similar to public Medicare. But there may be restrictions on eligibility, and some proposals limit the option to small employers, individuals, and the self-employed.

The number of currently insured persons who would switch to a public option is a matter of debate and conjecture. Different simulation models yield different estimates, depending on the assumptions on which the simulation is based. Given similar coverage, consumer behavior hinges primarily on the price differential between plans. The Lewin Group has estimated that 70 percent of those with private insurance would switch to a public plan if the latter's premiums were 30 percent lower. The numbers of those changing from private to public coverage would decrease directly with the cost differential. The Congressional Budget Office's estimates assume a much smaller gap in premiums, and therefore a lower propensity to switch. These projections are "if... then" kinds of statements with a high degree of uncertainty.

Why have this option?

The political leadership is divided on the type of health care system the U.S. should have, and having a public health option is seen as a compromise between those who want a market-driven solution under multiple insurers and those who favor uniform coverage with the government assuming responsibility for pooling revenues and paying providers (i.e., a single payer). Operating under government auspices — much like traditional Medicare — a public plan would not have the profit-maximization goal that is part of any entrepreneurial insurance venture. At the same time, it is proposed as one among other plans, allowing the private insurers to operate in a "non-disrupted" system.

The rationale for the public plan, in President Obama's words, is to give Americans "a better range of choices, make the health care market more

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competitive, and keep the insurance companies honest." The public option is therefore seen as a "benchmark" against which the performance of private insurance can be measured, and as a goad to make the insurers reform themselves.

A public health plan is expected to eliminate the insurance industry's practice of rejecting someone because of age or medical status. Moreover, it separates coverage from employment, and therefore gives consumers greater job mobility.

The current health insurance market is highly consolidated. For all the talk of unfettered competition, a handful of carriers dominate the insurance market: In 40 states, the top three carriers account for 60 to 100 percent of the market. The public option is therefore geared toward giving citizens more choices. In addition, the public option has the possibility of offering consumers a wider choice of doctors — that, rather than the choice of plans, tends to be more important to consumers.

The public plan is expected to spearhead innovations in access, quality control, and provider payment, thereby setting the standard for other plans to follow. How it is going to do this, however, is not at all clear.

How would it affect consumers?

Those who are insured, who lack secure workplace coverage, or who are dissatisfied with their current plan would have this option to consider. Moreover, a public plan that is not geared toward profits can presumably provide greater value-for-money. In states where the insurance market is highly concentrated, a public option has the potential of broadening consumer choices.

A recent survey carried out by Consumers Union indicates that two-thirds of the population support a public plan option competing alongside private insurers.

How would it affect providers?

Providers should not be unduly affected by having an additional Medicare-like plan. Indeed, they could gain from the expansion of coverage, as patients who fall into the "bad debt and charity pool" gain insurance. But the possibility of lost revenues is keeping some providers vigilant or downright adversarial. Hospitals are concerned that, if large enough, a public plan could exert pressure to keep costs down. Hospitals are also saying that, were this the case, they would have to charge other insurers more to make up the difference. This type of cost-shifting already occurs now to some extent.

The American Medical Association (AMA) is on record as opposing a new public plan because it "threatens to restrict patient choice by driving out private insurers." It is also fearful that cost-cutting may start with doctors, as they most often act as fiduciary agents on behalf of patients. While the AMA represents a minority of physicians and is no longer as politically powerful as it once was, it remains a vocal lobby and a strong contributor to congressional candidates.

Not surprisingly, insurers are in the vanguard of the opposition. They fear any option that may dilute their power, shrink their market, reduce their profits, and hold them accountable to stricter standards. To the extent the public option would do any of these, it would threaten the current operations of the insurance industry.

What are the implications in terms of cost?

A federal public insurance plan could benefit from a large risk pool (therefore avoiding the volatility of small numbers) and from economies of scale, thereby exerting downward pressure on costs. In addition, the plan would be able to leverage its clout vis-à-vis providers, negotiating rates that are below those of the commercial carriers. This latter possibility worries physicians and other providers who would lose part of their current bargaining power. Opponents of the plan fear that, because the plan would not need to make a profit, it could offer coverage for less, thereby competing advantageously vis-à-vis commercial insurers. As indicated earlier, the full impact of this would depend on the public vs. private difference in premiums.

What effect would it have on quality?

The expectation is that a public plan would be more innovative than the existing private options, which are wedded to tradition and the protection of their bottom line. Some of the innovations aimed at enhancing quality include making better use of electronic medical records and other health information technology, providing incentives for the adoption of "best practices," and paying for outcomes rather than volume.

At present, we know that Americans receive approximate health care only 55 percent of the time. Many health care services are therefore ineffectual, unnecessary, and even downright dangerous. Addressing this quality gap is an obvious way to enhance quality and control costs. At present, however, neither private insurers nor the existing public plans (Medicare and Medicaid) have a good track record monitoring their services to ensure that they reflect "best practices."

Why is the option so strongly opposed by some, including Public Citizen?

Those on the right see the public option as a way to get government more involved in the health care market. Senator Judd Gregg (R-N.H.), for example, feels that many Republicans view a public plan as "a stalking horse for a single-payer system." Because they see any public plan as a way to undermine the private insurance market, they are opposed to the public option. Some see the public plan as an entering wedge for a single-payer system, which

would provide uniform coverage to everyone. Interestingly, those who favor private insurance are afraid that private carriers would not be able to compete against a government plan, and that the latter would therefore prevail, ultimately becoming the nation's sole health insurer.

At the same time, the public option is also strongly opposed by those who, like the Public Citizen Health Research Group, advocate a single-payer system. The argument here is that the public option will not be able to exert enough leverage to control costs and insure quality, would not reduce the massive administrative waste that accompanies multiple payers, nor could it afford to pay for the uniform coverage necessary for equality in health care access. Moreover, the virtues of the public option raise the following question: If the public option were to provide equal or better care at lower cost, why not cover everyone at the outset, thereby assuring equality of access, greater accountability, and a greater probability of controlling costs? Single-payer advocates feel that the public plan option route would be a diversion from the ultimate goals of access, quality, and cost control and would require the nation embarking on another major reform effort in another decade, during which time tens of thousands more Americans would die because of a lack of health insurance.

What does it mean to have all insurance options operating on an 'even playing field'?

Private insurers are concerned that a public plan would have intrinsic advantages and be protected against the vagaries of the health care market. Because a large federal plan could have an unfair pricing advantage, they are proposing measures to offset this and create an "even playing field." They are therefore requiring that all plans, whether private or public, be self-sustaining (its financial base relying on payments and premiums rather than on tax dollars) and that any public plan be required to maintain a reserve similar to that of private insurers. Senator Charles Schumer (D-N.Y.) has been particularly adamant in arguing that all insurers should be subjected to the same rules, and that those who operate a plan should be independent from those who regulate it.

An "even playing field" can also mean that all insurers offer a given benefit package, so that they compete on the basis of cost. This is very different from the way the health insurance market works at present. Most insurers offer a variety of packages at different premiums, and consumers find it difficult to identify what trade-offs they are making when facing different services and price tags.

What does this issue mean politically?

President Obama has made it clear that health reform is one of his priorities. He and his health policy advisors have repeatedly advocated on behalf of a public plan. While they have not described the issue as "non-negotiable," they are pressing for its inclusion in any legislation to be seriously considered.

The legislative branch is very divided on the matter. Indeed, the issue of the public option has become a surrogate for health reform in general. Republicans regard the inclusion of a government-run plan as a major threat that could jeopardize bipartisan support for any reform legislation. One report describes the issue as a dealbreaker, Republicans contending that "no matter how a public plan is designed, it would inevitably balloon and crush the private market."

Some Republicans who feel that the Democrats will not concede on the public plan are proposing a compromise based on a "trigger." This would allow the public option to be enacted only if the private insurers fail to meet certain performance criteria. The debate would then hinge on the criteria for the "trigger" going into effect, and the argument would shift into the arcane language of "insurancespeak." ◆

Hospitals Drop the Ball on Physician Oversight

The following is the executive summary of Public Citizen's report, "Hospitals Drop the Ball on Physician Oversight," which examines and presents possible improvements to address deficiencies in national reporting of hospital disciplinary actions. The full report is available at http://www.citizen.org/publications/release.cfm?ID=7659&secID=1158&catID=126.

The National Practitioner Data Bank (NPDB) was established by the Health Care Quality Improvement Act of 1986 to protect patients from questionable physicians. The legislation included a requirement that hospitals report to the NPDB whenever they revoke or restrict a physician's hospital privileges for more than 30 days for problems involving medical competency or conduct.

As the only national repository for the records of doctors disciplined by their peers for unprofessional or incompetent behavior, the usefulness of the databank has been historically handicapped by the failure of thousands of hospitals to report to the NPDB. As of December 2007, almost 50 percent of the hospitals in the U.S. had never reported a single privilege sanction to the NPDB. Prior to the opening of the NPDB in September 1990, the federal government estimated that 5,000 hospital clinical privilege reports would be submitted to the NPDB on an annual basis, while the health care industry estimated 10,000 reports per year. However, the average number of annual reports has been only 650 for the 17 years of the NPDB's existence, which is one-eighth of the government estimate and about one-sixteenth of the industry estimate.

Hospital reporting varies by state. For example, about 70 percent of the hospitals in Louisiana have never reported, while only about 25 percent of the hospitals in Connecticut have not reported.

Public Citizen, through its Health Research Group, compiled this report by reviewing a number of studies by the Office of Inspector General (OIG), work by the Citizen Advocacy Center, (CAC), medical journal articles, and recommendations from an October 1996 national meeting on hospital underreporting. Public Citizen also analyzed the NPDB Public Use File to examine the relationship between hospital reports and actions taken by state medical boards on the same physicians.

Low hospital reporting of doctors raises questions about the effectiveness of hospital peer review.

Operated by the Health Resources and Services Administration (HRSA), part of the Department of Health & Human Services (HHS), the NPDB was designed as a searchable resource for hospitals and other medical entities to check practitioners' backgrounds and to consider taking their own action based on the information in the databank. Prior to its launch, this function was not being provided in any systematic way. The NPDB's goal was to reduce the likelihood that disciplined doctors might continue to injure patients by relocating to another hospital or state where their reputations and track records were not known.

The OIG at HHS did an initial assessment after the NPDB had been in operation for three years. This assessment found that a wide variation in reporting rates from state to state could suggest differences in the quality of care rendered, or perhaps in the capacity or willingness of hospitals to discipline doctors and to submit reports to the NPDB. In response to the OIG report, HRSA convened a national conference in October 1996 of many stakeholders such as the American Hospital Association (AHA), American Medical Association (AMA), the Joint Commission on Accreditation of Healthcare Organizations ("Joint Commission"), Center for Medicare and Medicaid Services (CMS), Public Citizen, and OIG. The consensus report from the conference found that the number of reports in the NPDB is unreasonably low, compared with what would be expected if hospitals pursued peer review effectively.

Collectively, the OIG report, the 1996 national conference, and a 2002 HRSA-funded study of hospital compliance made a total of 10 different recommendations to remedy this serious problem. However, as of Dec. 31, 2008, only one of the recommendations has been fully implemented.

The Journal of the American Medical Association has called hospital peer review one of the pillars of quality assurance in the United States. Low hospital reporting of doctors raises questions about the effectiveness of hospital peer review. Underreporting to the NPDB suggests that hospital peer review is not fulfilling the public trust.

Our review identified and focused on two factors associated with under-reporting: failure of hospitals to report and failure of hospitals to take action on questionable physicians. For example, a HRSA-funded study reported in the *American Journal of Public Health* noted that, to avoid reporting, hospitals imposed disciplinary periods of less than 31 days, thereby avoiding the need for reporting physicians to the NPDB; a medical board official informed Public Citizen that some hospitals avoid reporting by changing their bylaws or by having physicians take a "leave of absence." In one of the most egregious recent examples of the breakdown of hospital peer review, two physicians at Redding Medical Center in Redding, Calif., performed clearly unnecessary bypass and valve surgery between 1992 and 2002 on hundreds of patients. Peer review of

the cardiac program and discipline of these physicians was not done because of the "prestige" of one of the physicians involved and the revenue for the hospital generated by the surgeries. Furthermore, although both state and Joint Commission surveys had identified peer review deficiencies at Redding, there was no oversight follow-up.

State medical board officials report that hospital clinical privilege sanctions are a valuable source of information for identifying physicians with performance or conduct problems, and many boards use this information to launch investigations that can lead to disciplinary action. However, our analysis of the NPDB Public Use File found that almost 1,000 physicians who had at least two adverse clinical privilege reports to the NPDB did not have any subsequent licensure board disciplinary action. One physician had nine adverse clinical privilege reports but no licensure board actions.

Public Citizen's report offers the following specific recommendations for making hospital peer review, hospital reporting, and hospital oversight more accountable to the public:

1. HRSA and CMS should work together to achieve a regulatory and statutory change so that the Medicare conditions of participation specifies hospitals' reporting responsibilities under the Health Care Quality Improvement Act.

2. CMS should require that the standards for compliance with the Medicare conditions of participation include all aspects of peer review.

3. Congress should provide CMS with the authority to impose sanctions on hospitals and physicians for failure to perform peer review.

4. Congress should amend the Health Care Quality Improvement Act to impose a civil money penalty for failure to report.

5. HRSA should also seek legislative authority for conducting compliance reviews of clinical privilege reporting, including authority to access peer review records.

6. The Office of Inspector General should review hospital practices relating to granting and renewing privileges.

7. HRSA should initiate educational and compliance activities involving hospitals that have not reported.

8. HHS should implement specific recommendations from the 1996 Chicago National Conference on Under-Reporting:

- The conference recommended that HRSA study the problem further, possibly through case studies. As soon as possible, HRSA should address the issue of "peer review immunity." Notwithstanding the peer review immunity protection afforded by NPDB legislation, hospitals apparently remain concerned about lawsuits. HRSA should update the survey of court decisions that was prepared for the October 1996 national conference in Chicago. As noted earlier, the survey concluded that the immunity provisions of the Act were protecting professional review activities in the vast amount of cases. HRSA should make results of the updated survey available to the AHA and AMA to share with the hospital and medical community, respectively.

- The 1996 national conference recommended that the Joint Commission make reporting by hospitals of adverse actions taken against hospital privileges a specific point of review. Following the national conference, HRSA and CMS wrote the Joint Commission asking for assistance. To date, the Joint Commission has not taken steps to include hospital reporting in its accreditation surveys. The Joint Commission should amend its standards to incorporate compliance with NPDB reporting.

9. State medical boards should request their respective state legislatures to adopt those provisions of the CAC model act that have the potential to increase reporting.

10. State medical boards and HRSA should work together to facilitate reporting to the NPDB.

11. Congress should provide the Office of Inspector General, HHS, with authority to review state medical boards' handling of adverse clinical privilege reports.

12. Hospital compliance officers should monitor hospital peer review and reporting to the NPDB.

To achieve this, we specifically recommend the following:

- HRSA and the Health Care Compliance Association should work together in publicizing the NPDB reporting requirement through joint letters, webinars, and other training opportunities.
- The Health Care Compliance Association should include NPDB reporting in its agenda for national and regional conferences.
- The OIG should consider revising the Feb. 23, 1998 Compliance Guidance for Hospitals to include hospital peer review and NPDB reporting as risk areas.

13. The Office of Inspector General, HHS, should use corporate integrity agreements to assure hospital compliance with NPDB reporting requirements. ◆

A Dictionary of Health Policy Terms, Part III

The debate on health reform is creating a new vocabulary. Some of the new words or phrases are "old wine in new bottles"; others provide "handles" for innovative concepts. With so much wonky-talk making its way to the Internet and print media, consumers need a glossary to understand what policymakers are talking about. In 2007 and 2008, we published Parts I and II of a Health Policy Dictionary. Here, we present an update with some of the terms that are being bandied about with increasing frequency.

Accountable care organization: Better known by its acronym (ACO), this type of organization comprises a group of health providers responsible for the quality and cost of health care delivered to a given population. Avoiding the fragmentation that undermines accountability, ACOs most often include one or more hospital, primary care physician, and specialist. Under the model, providers are held accountable for the quality of care they deliver to patients and may receive bonuses for providing high-quality, low-cost care. They may also pay penalties for any care that fails to meet quality standards. The ACO is based on the premise that providers should be accountable for decisions about capacity (e.g., number of specialists, bed supply) that ultimately affect spending. Moreover, providers within an ACO have a vested interest in coordinating care and monitoring one another, because any gap in the network of services would affect their shared patients and reflect on the ACO as a whole.

ACOs have been tried under Medicare, and have succeeded in enhancing quality and keeping the lid on costs. The Medicare Payment Advisory Commission (MedPAC), is supporting the expansion of ACOs. It is also establishing the conditions under which ACOs would work. These include a minimum size (at least 5,000 patients) and a structure to make joint decisions on capacity, among others.

ACOs can be voluntary or mandatory. Under the voluntary model, Medicare provides physicians with rewards and few, if any, penalties. This modality is therefore referred to a "bonus-only" design. It has met quality objectives but has not generated savings. Under the second type of ACO, provider participation would be mandatory, and there would be both bonuses for good performance and penalties for bad performance. Shared savings (the result of modified practice patterns and constrained capacity) and penalties could fund the bonuses.

Bending the curve: Given soaring health care expenditures, covering the uninsured needs to be accompanied by cost-control measures. "Bending the curve" is seen as a reasonable goal, and refers to slowing down the rise in health expenses. The idea is not to reduce overall costs, but rather to slow down the pace of increase.

Although the Commonwealth Fund published a report with the title "Bending the Curve: Options for Achieving Savings and Improving Value in U.S. Health Spending" in 2007, the phrase entered the media lexicon when it was used by President Obama to refer to one of the goals of health reform.

Best practices are activities that, having been rigorously evaluated, demonstrate success, have had a favorable impact, and can be replicated. In medicine, these can vary by type of patient, practice, situation, and context. Nevertheless, there are a number of activities that have been tested and are generally accepted. These can cover disease prevention, screening, treatment, and rehabilitation. Best practices become the "gold standard" against which other interventions are measured.

Changing technology and an ever-expanding knowledge base are constantly modifying practices. What is "best" at one time may therefore become outmoded or obsolete. And because "best practices" vary by condition or age group, providers need to both stay up-to-date and match their interventions to the patients they serve.

Bundled payments: Practitioners and policymakers are increasingly recognizing that paying doctors and hospitals on a fee-for-service basis conflicts with the goal of providing access to affordable care. Fee-for-service rewards volume, often to the neglect of quality and value. It is intrinsically inflationary, and generates excessive services. These then become the norm, to the detriment of both patients and budgets.

Recognition that "more" is not necessarily "better" is now informing the debate on how to pay providers. One alternative is a bundled payment system, which covers costs of care across different settings of a patient's episode of illness over a given span of time. This payment system, also called "episode-of-care" payment, would be based on the current distribution of cumulative fee-for-service costs per episode. Medicare is already piloting bundled payments for some inpatient services as well as for some surgical services. Other providers are also experimenting with the modality for different diagnoses and chronic illnesses. The expectation is that, if successful, other payers would also adopt this payment approach.

If properly designed, bundled payments can enhance coordination of care, decrease unnecessary services, reduce costs, and increase accountability. But the logistics of "bundling" may be challenging. Some health care episodes lend themselves more to this type of payment than others: They have a clear beginning and end, and a predictable intensity of care. Operational decisions concerning bundling include deciding

what procedures and practitioners are part of the "bundle," how to deal with differences in services, and how to address the possibility of a patient switching providers mid-episode. (See also evidence-informed case rate and Prometheus payment model).

Comparative effectiveness research focuses on the rigorous assessment of the relative safety, effectiveness, and cost of treatments or other interventions to address a given condition. This type of research is designed to identify what works for whom, and at what cost. Decisions concerning what services to cover and at what cost would be based on the findings of this research. At present, the Agency for Healthcare Research and Quality conducts such research; their findings are used to improve health care quality for public programs such as Medicare, Medicaid and State Children's Health Insurance Program. Other types of comparative effective research are conducted by academic institutions, insurers, and providers. The results of these studies often determine "best practices" (defined earlier in the story).

Evidence-informed case rate (ECR) is a type of bundled payment in which the amount is clinically derived and risk-cushioned. It has an explicit profit margin built in. The ECR defines the boundaries of typical care and establishes a base payment for all services within the recommended clinical guidelines. The Prometheus payment model (see later in the story) uses this rate. The expectation is that the rate will promote coordination among providers involved in an episode of care and produce better outcomes for patients. This type of bundle is still experimental and will be carefully assessed.

Gateway is another name for an "insurance exchange" (defined later in the story).

Global budgets set expenditure caps for certain types of services. This gives providers some flexibility in allocating resources while providing them a target beyond which they could would not be reimbursed. Global budgets increase accountability and self-monitoring, and reduce overuse of resources. Because providers face a zero-sum game in which more for one necessarily means less for others, global budgets keep everyone honest.

Some countries such as France, Sweden, and Switzerland use global budgets to control hospital operating expenses. Others (e.g., Canada and the United Kingdom) use global budgets to cover both hospital and physician expenditures.

Individual responsibility: This phrase is being used to describe a requirement that everyone be insured against health care costs. A more subtle meaning of the term is that those who do not obtain insurance should be imposed a financial cost or penalty.

Insurance exchange refers to a mechanism for linking those seeking insurance with an array of options. It is intended to serve as a clearinghouse where buyers and sellers meet. The best-known health insurance exchange at the state level is the Massachusetts "Connector." This exchange does not regulate or purchase insurance, nor does it negotiate rates with carriers. Its main role is to facilitate transactions among parties. This includes providing information to consumers so that they can compare plans and assess trade-offs.

Medical home is the current lingo for a primary care provider that would serve as a point of entry and source of continuing care. Primary care practices would be charged with care coordination, care management, and referrals to appropriate care. A patient's medical home would also have a complete and easily accessible medical record, thereby minimizing the fragmented information systems that jeopardize integrated care.

Open-ended payments refer to the way providers are paid at present: Doctors and hospitals bill insurers for services rendered, with no limit or cap on what they can bill. If patients are covered by insurance, the carriers then have to sort out whether or not the payments are for covered services, and pay the agreed-upon fee for each service. Because this can be a labor-intensive process, U.S. net insurance administrative costs more than doubled between 2000 and 2008. The current system not only defies budgeting, but also siphons off a growing proportion of the health care dollars for administration. In international comparisons, the U.S. spends significantly more on high administrative overhead as a share of national expenditures and per person.

Prometheus payment model is a bundled payment modality that is being piloted in the private sector under the sponsorship of the Robert Wood Johnson Foundation. The model relies on evidence-informed case rates (see earlier in the story) and is initially limited to five procedural diagnoses and five chronic illnesses. The latter include congestive heart failure, chronic obstructive pulmonary disorder (COPD), asthma, coronary artery disease, and hypertension.

Shared responsibility has become a code for indicating that individuals, employers, and government will all have to do their part to pay for health care for all. While this may seem self-evident, this makes explicit the fact that health reform will have a fiscal effect on all stakeholders. "Shared responsibility" is also being used to distinguish an approach that gives a government a key role, in contrast to the "You're on your own" approach, which would rely primarily on tax incentives to expand coverage. ◆

Product Recalls

May 13, 2009 - June 16, 2009

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

DRUGS AND DIETARY SUPPLEMENTS

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

Recalls and Field Corrections: Drugs – CLASS I

Indicates a problem that may cause serious injury or death

Morphine Sulfate Immediate Release Tablets 15mg used as rescue medication in kits for clinical study KF5503/16, 100 count bottles, Clinical study KF5503/16; 1,070 bottles; Tablet Thickness; possibility of oversized tablets which could result in superpotent dose. Ethex Lot #: 81746; Almac Clinical Services LLC.

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

Daytrana (methylphenidate transdermal system), 10 mg, 30 patches per box, Rx only, NDC 54092-552-30; Defective delivery system (mechanical peel force out of specification). Lot #s: 2570611 (exp. date 04/30/2009), 2617011 (exp. date 06/30/2009), 2617111 (exp. date 07/31/2009), 2656911 (exp. date 08/31/2009), 3014511 (exp. date 05/31/2010), 2657212 (exp. date 08/31/2009), 3073511 (exp. date 05/31/2010), 2657211 (exp. date 08/31/2009), 2616311 (exp. date 05/31/2009), 2617211 (exp. date 06/30/2009); Noven Pharmaceuticals, Inc.

Daytrana (methylphenidate transdermal system), 15 mg, 30 patches per box, Rx only, NDC 54092-553-30; Defective delivery system (mechanical peel force out of specification). Lot #s: 2572011 (exp. date 05/31/2009), 2732811 (exp. date 09/30/2009), 27328111 (exp. date 09/30/2009); Noven Pharmaceuticals, Inc.

Daytrana (methylphenidate transdermal system), 20 mg 30 patches per box, Rx only, NDC 54092-554-30; Defective delivery system (mechanical peel force out of specification). Lot #s: 2617811 (exp. date 06/30/2009), 2624711 (exp. date 06/30/2009), 2625211 (exp. date 7/31/2009), 3051911 (exp. date 05/31/2010), 31947 (exp. date 07/31/2010), 31949 (exp. date 07/31/2010), 31951 (exp. date 07/31/2010), 33041 (exp. date 09/30/2010), 33042 (exp. date 09/30/2010), 34172 (exp 12/31/2010); Noven Pharmaceuticals, Inc.

Daytrana (methylphenidate transdermal system), 30 mg, 30 patches per box, Rx only, NDC 54092-555-30; Defective delivery system (mechanical peel force out of specification). Lot #s: 2572411 (exp. date 05/31/2009), 2572611 (exp. date 05/31/2009), 2573211 (exp. date 06/30/2009), 2573311 (exp. date 06/30/2009), 2573411 (exp. date 06/30/2009), 2652411 (exp. date 08/31/2009), 2733111 (exp. date 09/30/2009), 2737411 (exp. date 10/31/2009), 2750111 (exp. date 11/30/2009), 3015011 (exp. date 05/31/2010), 3015311 (exp. date 05/31/2010), 31739 (exp. date 06/30/2010), 31920 (exp. date 06/30/2010), 31921 (exp. date 06/30/2010), 31922 (exp. date 06/30/2010), 31923 (exp. date 06/30/2010), 2733211 (exp. date 09/30/2009); Noven Pharmaceuticals, Inc.

Sore Throat Lozenges, Pastillas para el dolor de la garganta, (Benzocaine 6mg and Menthol 10mg), 100 Lozenges. UPC Code 0 92265 08450 5; 726 boxes each containing 100 lozenges; Misbranded; product labeled to contain Benzocaine and Menthol actually contains Hexylresorcinol. Codes are for products manufactured from 3/3/2008 through 3/24/2009 as follows: C0038, C0198, D0088, E0058, F0248, I0084, K0198 and B02690511; First Aid Only Inc.

Furosemide Tablets, USP, 40 mg, 1,000 Tablets, Rx only, 0781-1966-10; 5773/1000 tablet bottles; Furosemide tablets were out of specification for tablet thickness and potency. Lot number: 180974 exp. date 12/2011; Sandoz, Inc.

Metoprolol Tartrate Tablets USP, 100 mg, 1,000 count bottles, Rx only, NDC number 0093-0734-10; 2,108 bottles; The affected lots may contain some tablets exceeding weight requirements. Lot #s: 505514 (exp. date 01/2010), 505515 (exp. date 01/2010), 505516 (exp. date 01/2010), and 505517 (exp. date 01/2010); Teva Pharmaceuticals USA.

Zicam Multisymptom Cold & Flu Nighttime Formula, (Acetaminophen 325mg, Detromethorphan HBr 10mg and Guaifenesin 200mg) 8oz bottle. NDC 62750-023-10; UPC code: 732216 30032 1; 20,365 bottles; Mislabeled; some bottles in the lot contain an incorrect Drug Facts panel on the bottle. Bottle labeled as containing Guaifenesin actually contains Doxylamine Succinate. Lot: MSN8287-1, exp. date 10/2010; Unicep Packaging Inc.

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 its 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; Recall Information

13-foot Square Trampolines. The straps supporting the top of the trampoline's enclosure to the poles can fail. The enclosure could drop if these straps break, posing a fall risk. Skywalker Holdings LLC, (866) 603-5867 or www.skywalkertrampolines.com.

2005 Novara Trionfo Bicycles. The fork can separate from the steerer tube, which can cause the rider to lose control. Recreational Equipment Inc. (REI), (800) 426-4840 or www.rei.com.

2009 Widetrak Snowmobiles and Engine Block and Battery Heaters. The insulation of the electrical cord for the engine and battery heaters can fail during cold temperatures, posing an electric shock hazard to consumers. Polaris Industries Inc., (888) 704-5290 or www.polarisindustries.com.

39" St. Anne Acacia Benches. The bench frame can collapse when weight is placed on it, posing a fall hazard to consumers. Ross Stores Inc., (877) 455-7677 or www.rossstores.com.

Bicycles with JD Suspension Forks. The recalled bicycle's fork can lose alignment causing the front wheel to turn unexpectedly. This can cause the rider to lose control of the bicycle and crash. Trek Bicycle Corp., (800) 382-2453 or www.trekbikes.com.

Bicycles with JD Suspension Forks. The recalled bicycle's fork can lose alignment causing the front wheel to turn unexpectedly. This can cause the rider to lose control of the bicycle and crash. Cannondale Bicycle Corp., (800) 245-3872 (BIKEUSA) or www.cannondale.com.

Bonavita "Cabana" Drop Side Cribs. The wooden crib slats can detach or break creating a gap, which can pose an entrapment and strangulation hazard to infants and toddlers. LaJobi Inc., (866) 688-9009 or www.LaJobi.com.

Bonavita "Hudson" and Babi Italia "Pinehurst" Drop Side Cribs. The lower spring pins on the footboard and headboard can pop out of the tracks located on the drop side causing the drop side to detach from the crib. When the drop side detaches, it creates a hazardous gap between the drop side and the crib mattress in which infants can become entrapped and suffocate or fall from cribs. LaJobi Inc., (866) 688-9009 or www.Lajobi.com.

Bugaboo Bee Strollers. One or both sides of the brakes can fail, causing a stroller to unexpectedly roll away on an incline. This can pose a risk of injury to the child occupant. Bugaboo North America Inc., (800) 460-2922 or www.bugaboo.com.

Bunn® Single Cup Pod Brewers. The pod drawer of the pod brewer can open unexpectedly during a brew cycle, posing a burn hazard. Bunn-O-Matic Corp., (800) 741-3405 or www.bunn.com.

Children's Loungewear Garments. The loungewear garments fail to meet children's sleepwear federal flammability standards, which require sleepwear, including loungewear, to be either snug-fitting or flame resistant. Warm Biscuit Bedding Co., (800) 231-4231 or www.warmbiscuit.com.

Composite Decks. The recalled decking can prematurely deteriorate and unexpectedly break. Consumers can fall through broken decking and suffer serious injuries. Louisiana-Pacific (LP) Corp., (888) 325-1184 or www.deckingnotice.com.

Cumberland Outfitters Girl's Hooded Sweatshirts. The sweatshirts have a drawstring through the hood, which can pose a strangulation hazard to children. In February 1996, CPSC issued guidelines to help prevent children from strangling or getting entangled on the neck and waist drawstrings in upper garments, such as jackets or sweatshirts. Ely and Walker, (800) 359-1878 or www.elyandwalker.com.

CONSUMER PRODUCTS

Eddie Bauer Soothe & Sway Play Yards. The rocking bassinet attachment can tilt even when secured by straps in the non-rocking mode or can stay tilted without returning to sleeping level, causing an infant to roll to the corner or side of the bassinet. The infant can then become wedged or pressed against the side or bottom of the bassinet, posing suffocation risk. Dorel Juvenile Group Inc., (888) 233-4903 or www.djgusa.com.

Fluke Digital Clamp Meters. The meters can fail to give an appropriate voltage reading, resulting in the operator falsely believing the electrical power is off, posing a shock hazard. Fluke Corp., (888) 983-5853 or www.fluke.com/33Xrecall.

Folding Toy Beach Chair for Stuffed Animals. This toy chair legs can bruise, pinch or cut fingers if caught while folding. Build-A-Bear Workshop®, (866) 236-5683 or www.buildabear.com.

Fushin ATVs. These ATVs lack front brakes, a tire pressure gauge, and padding to cover the sharp edges on the handlebar assembly, which could pose a risk of injury to young riders. Fushin USA LLC, (866) 659-8600 or www.fushinusa.com.

Lithium-ion Batteries Used in Hewlett-Packard and Compaq Notebook Computers. The recalled lithium-ion batteries can overheat, posing a fire hazard. Hewlett-Packard Co., (800) 889-2031 or www.hp.com/support/BatteryReplacement.

National and Sanyo Hand-Held Hair Dryers. The hair dryers are not equipped with an immersion protection device to prevent electrocution if the hair dryer falls into water. Immersion protection devices, which prevent electrocution, are required by industry safety standards for all electric hand-held hair dryers. Vintage International Inc., (888) 711-4656.

Norco Bicycle Frames. The bicycle frame can crack and separate, causing a rider to fall from the bicycle and suffer injuries. Norco Performance Bikes, (800) 663-8916 or www.norco.com.

Offset Patio Umbrellas. The patio umbrella could tip over and strike consumers if the umbrella's collar or sleeve is not removed prior to closing the umbrella, posing a risk of impact injury. The Home Depot, (866) 403-5504 or www.homedepot.com.

Outdoor Playset Gliders. The retaining rings used to secure the gliders to the playset can become loose or detached, posing a fall hazard to children. Backyard Play Systems LLC, (866) 890-2211 or email customerservice@backyard-play.com.

Samsung "Jitterbug" Cell Phones. The recalled cell phones that are in a no-service area and display an "out of range, try again later" message could fail to connect to emergency 911. Samsung Telecommunications America, (866) 304-4980 or www.samsung.com.

Skinner Knife Sheaths. The knife can cut through the sheath because there is no blade guard in the sheath. This poses a laceration hazard to consumers. Browning, (800) 637-0230 or www.browning.com.

Speedy Children's Hooded Zipper Jackets and Kids Hooded Pullover Jackets. The jackets have a drawstring through the hood, which can pose a strangulation hazard to children. In February 1996, CPSC issued drawstring guidelines to help prevent children from strangling or getting entangled on the neck and waist drawstrings in upper garments, such as jackets or sweatshirts. Winterbee Inc. d.b.a. Speedy, (888) 901-8067.

Starbucks Barista® Blade Grinders and Seattle's Best Coffee® Blade Grinders. The grinder can fail to turn off or can turn on unexpectedly, posing a laceration hazard to consumers. Starbucks Coffee Co., (866) 276-2950 or www.starbucks.com.

Step2 Play Up Gym Play Sets. The triangular hangers that attach the swing's ropes to the upper rail of the play set can break, posing a fall hazard to children. The Step2 Company LLC, (800) 347-8372 or www.step2.com.

Twin, Twin Extra-Large, and Twin Over Full Bunk Beds. The bunk beds do not have sufficient headboards, footboards, or guardrails and have gaps between parts of the upper bunk that could allow a child's body to pass through but not a child's head. These bunk beds pose a fall, entrapment, and strangulation hazard to children and violate the spacing requirements of the federal bunk bed safety standard. Gothic Cabinet Craft Inc., (877) 946-8442 or www.gothiccabinetcraft.com.

Viking Built-In Side-by-Side Refrigerator/Freezers and Refrigerators with Bottom Freezers. The refrigerator's doors can detach, posing an injury hazard to consumers. Viking Range Corporation, (888) 345-2650 or www.vikingrange.com.

Wolfgang Puck Toaster Oven/Toasters. The toaster oven can remain "on" after the toast pops up, posing a fire hazard. Wolfgang Puck, (800) 275-8273 or ovenrec@wphousewares.com.

OUTRAGE from page 12

The Supreme Court has treated discrimination based on language as equivalent to national origin discrimination. The court has therefore interpreted Title VI to ban language discrimination. Similarly, the federal government treats language as a proxy for national origin: In federally funded programs and activities, those who speak a language other than English are entitled to treatment equal to that received by English speakers. And because the overwhelming number of hospitals and many ambulatory care clinics receive federal funds, they should be held to this standard.

But there is no way to monitor compliance with the legal requirement. Even major medical centers in cities such as New York and Washington, D.C. fail to provide services for so-called LEP (limited English proficiency) patients. In the absence of planning and resources, stopgaps reign. Non-health care employees or patients in the facility may be called upon to serve as translators, a makeshift arrangement that does not assure accuracy and violates patient privacy.

The Office for Civil Rights (OCR) of the federal Department of Health and Human Services (HHS) is charged with making sure that programs under its aegis are free of discrimination. And its purview is wide: It includes any organization or individual that receives monies through HHS. This encompasses health departments, health plans, social service agencies, nonprofits, hospitals, clinics, and practitioners.

But OCR has no way to exercise its oversight function preventively and systematically. Instead, it often reacts to complaints, initiating reviews and investigating cases brought to its attention. Major medical centers in Boston and San Francisco, among others, have been the target of OCR complaints on behalf of LEP patients. These cases have resulted in the launching of solid interpreter services to address the complaint.

In attempting to comply with the federal requirements, however, most states have enacted a hodgepodge of laws and guidelines. The result, as stated in an article in the *Journal of General Internal Medicine,* is "a haphazard patchwork of legal obligations which vary from state to state, from language to language, from condition to condition, and from institution to institution." Not surprisingly, some initiatives reflect the political agendas of special interest groups. Their goal is therefore more to convey a political message than to meet patients' health needs.

Some states are aware that language can affect care and lead to adverse effects and misuse of resources. They are therefore taking steps to remedy the situation. Some are requiring continuing education for health professionals to address issues of language access and/or cultural competency. Washington State has established a health care interpreter certification program to insure that those serving in that capacity meet given standards of competence and knowledge. And 12 states and the District of Columbia have indicated that language services are eligible for federal matching funds under their Medicaid/State Children's Health Insurance Program. These efforts, while commendable, have not been incorporated into a "best practices" framework for other jurisdictions to replicate. They are therefore too hit-or-miss to affect large segments of the population.

The current debate on health care reform is focusing on expanding access, insuring quality, and controlling costs. Language is intrinsic to each of these goals. Without the ability to communicate, there is no access. And miscommunication is a major cause of medical errors and patient dissatisfaction, both obstacles to quality care. A national study carried by research from University of California-Irvine found that language barriers between patients and health care providers result in longer hospital stays and medical errors, both of which increase costs. Committing to universal health care means taking into account that language matters. ◆

THE PUBLIC CITIZEN HEALTH RESEARCH GROUP
Health Letter

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Language Matters: Poor Communication Can Mean Poor Health Care

A woman reads the label on her prescription drug and thinks she understands it. It says "take once after breakfast." But she is Spanish-speaking and "once" in Spanish means "eleven"; she therefore takes 11 pills after her café con leche.

An 8-year-old child accompanies his grandfather to the doctor. The elder gentleman does not speak English, so both he and the physician rely on the child to translate. The child speaks English but can neither fully understand nor convey what the health providers say. Yet everyone is lulled into thinking that information is being exchanged.

While much of the health care debate is being guided by how the arguments for or against reform are "framed," policymakers are paying scant attention to a more basic linguistic issue: many persons are deprived of adequate care because they are unable to communicate with their providers. Language barriers are very real and affect how care is provided and received. At present, patients are more multilingual than practitioners. The most recent Census data show that, in the U.S., one in five persons speaks a language other than English at home. This proportion ranges from 42.6 percent in California to 2.3 percent in West Virginia.

The law, however, is clear: All persons in the United States have a right to language-assistance services when attempting to get access to health care services. This is part of Title VI of the 1964 Civil Rights Act, which states, "No person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving federal financial assistance."

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