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Inside: *Bioterrorism Watch*

# Medical Ethics Advisor.

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Special Report:
Ethics in the bioterrorism age

# Anthrax scare sparks public pandemonium and a run on a powerful antibiotic

*Choice between calming patients, protecting public*

Despite the pleas of public health officials and even the American Medical Association (AMA), panic over recent anthrax cases in Florida, Washington, DC, and New York has pushed prescriptions for Cipro — the primary drug designated as treatment for anthrax exposure — to almost double the number normally prescribed at this time of year.

A national survey of retail and mail-order pharmacies, conducted by the drug-marketing consultant NDCHealth of Atlanta, found that prescriptions for Cipro during the months of September and October increased approximately 49% over the amount written during the same time period last year. (Ciprofloxacin is manufactured under the brand name Cipro by West Haven, CT-based Bayer AG.)

"Pharmacists are telling us they are getting a lot of prescriptions for Cipro, and when they call the physicians to question the prescriptions, the patients are getting extremely irate with the pharmacists — asking why they are even questioning the medication," says **Carmen Catizone**, MS, RPh, executive director of the National Association of Boards of Pharmacy in Park Ridge, IL. "The doctors are indicating to them, 'Go ahead and give it to them. They haven't been exposed to anthrax, but

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## COMING IN FUTURE ISSUES

- Establishing a context for bioethics in rural areas
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they are driving me crazy.'"

"We are not pleased with that, but it is the doctor's prescription," he continues. "Pharmacists are getting upset that they are put in the position of being the nation's police officers for the public's use of Cipro."

Public health experts worry that the rash of inappropriate prescribing will significantly contribute to the spread of antimicrobial-resistant organisms and will gut the effectiveness of ciprofloxacin, one of the newer class of fluoroquinolone antibiotics often used to treat infections that are resistant to most other medications.

"Cipro is our only option for some organisms that are resistant to older antibiotics," explains **Stephen Lerner**, MD, chief of infectious diseases at Wayne State University School of Medicine in Detroit, and a member of the Michigan Antibiotic Resistance Reduction Coalition. "If resistance develops to ciprofloxacin, we may be faced with infections for which there is no readily available treatment."

Bacteria rapidly evolve and develop resistance to antibiotics they are exposed to. The more prevalent the use of a particular antibiotic is in the general population, the more likelihood exists that more bacteria will be exposed and develop resistance, says Lerner. For example, resistance often develops when a patient takes a prescribed medication, but does not take it for the prescribed length of time.

The medication may indeed kill enough bacteria to treat that infection, but stopping the medication early may allow some bacteria to survive; these will be resistant to the antibiotic taken.

These resistant bacteria may either reinfect the original person or spread to, and eventually infect, other people. Most people have a certain amount of bacteria harmlessly residing in or on their bodies. If a person takes an antibiotic and does not have a bacterial infection, these harmless bacteria will "breed" resistant organisms.

For years, infectious disease specialists have urged physicians to curb inappropriate prescribing of antibiotics, asking that physicians ensure patients are getting them only for bacterial infections because antibiotics are useless against viral infections. In addition, specialists recommend that physicians prescribe newer, broad-spectrum antibiotics only when they feel an infection may be resistant to the older medications.

But physicians often feel pressured by patients and parents of children to prescribe an antibiotic, even when unnecessary in order to "cover all the

bases" and alleviate patient fears, says Catizone.

This is particularly true in the current situation, he says. Some pharmacists in New York and Washington have reported that patients were getting prescriptions of Cipro to have on hand "just in case" they were exposed to anthrax and there was a shortage of medication. Some physicians are frightened as well, with some reportedly prescribing Cipro for friends and family members to stockpile.

"I was getting calls — six to eight a day — asking for antibiotics, asking 'Can I have ciprofloxacin for myself, my wife, and my children?'" **Matthew Parker**, MD, a Washington, DC, internist, told *Reuters* news service on Oct. 15.[1] "I knew that I had chosen on my own to have it available. What is good for myself and my family is what I should do for my patients."

That view is likely shared by many physicians, Lerner says. "Physicians are trained that their first duty is to their patients as individuals, not to the community as a whole," he adds. Particularly in areas that have seen anthrax cases, physicians might feel there is a real potential for anthrax spread and agree to prescribe Cipro for worried patients.

"I think they see patients who are distraught," Catizone says. "And from a clinical sense, they feel that they can do something for [these] patients to alleviate their anxiety and prevent them from doing something very risky. They feel that they know that the antibiotics won't hurt the patients and might be able to help."

However, Cipro is not a totally benign drug. While approved by the U.S. Food and Drug Administration (FDA), its use has been associated with significant side effects, according to information provided by the FDA's Center for Drug Evaluation and Research.

Reported side effects include central nervous system problems including dizziness, confusion, tremors, hallucinations, depression, and increased risk of seizures; drug interactions (may increase levels of theophylline and caffeine, and other vitamin and drug products may reduce the effectiveness of Cipro); hypersensitivity, pseudomembraneous colitis, tendonitis, and tendon rupture; and photosensitivity.

The potential risk of these side effects may be considered reasonable for patients with an infection, but would not be an appropriate risk for patients not known to be infected or exposed to a dangerous organism, **Timothy T. Flaherty**, AMA chair warned physicians in a statement released

## CME questions

21. Prescribing ciprofloxacin for patients without any indication they have a resistant bacterial infection can be harmful because:
    A. It contributes to a shortage in local supply, and these drugs may be desperately needed by those who are ill.
    B. It contributes to development of bacteria that are resistant to the antibiotic, one of the few available to treat bacteria already resistant to older antibiotics.
    C. Significant side effects have been associated with ciprofloxacin, risk of these side effects may be reasonable in persons with a dangerous infection, but are not in people who are well.
    D. all of the above

22. Pharmacists are worried about on-line ordering of prescription drugs because:
    A. Some of the web sites selling drugs do not ask patients to provide a physician's prescription.
    B. Previous investigations have found that some products ordered this way are not of the appropriate quality or dosage mandated by the Food and Drug Administration for legal sale in this country.
    C. People often order large quantities of popular drugs to "stockpile," which creates a supply shortage in specific areas.
    D. all of the above

23. The anthrax vaccine made by BioPort, Inc.:
    A. is, except for the amount currently held by the military, quarantined because the manufacturing plant has not passed recent FDA inspections.
    B. should be made available to the public because it has been deemed safe and effective.
    C. has not been proven effective at preventing anthrax infection.
    D. has been shown to have a definite link to Gulf War Syndrome.

24. When communicating information to the public during crisis situations, hospital officials should:
    A. offer as much information as possible as long as, to the best of their knowledge, the information is accurate at the time.
    B. coordinate releases of information with other involved agencies and organizations, release only information that is verifiable and useful to the public, and refuse to engage in speculation.
    C. wait until they have useful, verified information before addressing the public at all.
    D. all of the above

Oct. 17. "All antibiotics have side effects," Flaherty said, urging physicians and the public not to hoard antibiotics. "In the absence of an actual infection, only the risk remains."

Stockpiling Cipro also is dangerous because symptoms not related to anthrax may prompt people to initiate unnecessary treatment with the powerful drug, he added.

"The AMA continues to stress that there is no indication for the widespread prescription of antibiotics to prevent anthrax, and no indication for the prescription of antibiotics to have on hand in case of a future incident."

Lerner disagrees with the argument that physicians should avoid prescribing "preventive" Cipro because of the reported side effects. "I don't really think that is an issue. Cipro is a safe drug — all drugs have the risk of some side effects — and I don't want to give the impression that it is not," he says. "The real problem is the potential for the spread of antibiotic resistance."

Physicians need to be supported by their local hospitals and health care systems, which can work to calm public fears and educate people about the need to preserve these antibiotics for the people who need them.

The Centers for Disease Control and Prevention (CDC) in Atlanta has several support resources available for physicians who need help talking to their patients about appropriate antibiotic usage, Lerner adds.

For more information, see the CDC's web site at: http://www.cdc.gov/antibioticresistance.

"The key is the gatekeeper as the physician," says Catizone. "If he or she writes those prescriptions, that begins the whole process. They have to be able to say to the patient, 'I can't prescribe this for you, that's not what it is indicated for.'"

### Reference

1. Fox M. Doctors struggle with demands for anti-anthrax drug. *Reuters*, October 15, 2001. Accessed on Nov. 2 at: http://dailynews.yahoo.com/h/nm/20011015/sc/attack_anthrax_doctors_dc_1.html. ■

**SOURCES**

- **Stephen Lerner**, MD, Michigan Antibiotic Resistance Reduction Coalition, 333 W. Fort St., Suite 1500, Detroit, MI 48226.
- **Carmen Catizone,** 700 Busse Highway, Park Ridge, IL 60068.

# FDA targets web sites selling unapproved drug

*Virtual pharmacies get warning from the FDA*

Although physicians and pharmacists have been concerned for some time about the emergence of "virtual" pharmacies that sell prescription drugs over the Internet, the situation has been made critical by some entrepreneurs' response to the anthrax attacks.

On Nov. 1, the U.S. Food and Drug Administration (FDA) issued warnings to 11 international Internet vendors who were offering generic ciprofloxacin for sale to American consumers.

"The FDA is unable to determine whether these products were made in accordance with U.S. specifications and, therefore, their sale and distribution in the U.S. may be illegal," reads a statement issued by the administration.

A recent on-line search performed by *Medical Ethics Advisor* turned up more than 34 hits for sites offering Cipro prescriptions on-line. With names such as "www.2-buy-cipro-online-4-anthrax-bacteria-resistance.com/" and "www.cipro-anthrax-cure.com," many sites require no prior physician's prescription and offer on-line consultations and approvals. After Nov. 1, many of the sites were no longer accessible or featured revised statements advising consumers to contact their private physician or public health department if they were concerned about anthrax exposure.

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According to the FDA announcement, the agency is warning U.S. citizens that foreign drugs promoted on the Internet may not be approved for marketing in this country and may not be legally imported.

The agency is informing regulatory officials in the countries in which the Internet pharmacies operate that these potential violations are taking place, and it is advising the U.S. Customs Service that shipments from these vendors may be detained and refused entry.

In addition to the foreign web sites, some pharmacists are concerned about the proliferation of web sites in this country that offer prescription drugs on line, including sites that "bypass" the need for a doctor's prescription by providing on-line "consultations," says **Carmen Catizone**, MS,

RPh, executive director of the National Association of Boards of Pharmacy (NABP).

The association is asking consumers to buy only from on-line pharmacies that are approved through its Verified Internet Pharmacy Practice Sites (VIPPS) program.

The VIPPS seal on the pharmacy's web site certifies that the pharmacy is properly licensed with the appropriate state boards of pharmacy and has met a rigorous criteria review that considers the site's protection of patient confidentiality, the authenticity and validity of prescriptions, a quality assurance program, and patient-pharmacist consultation. The following on-line pharmacies are VIPPS certified:

- accuratepharmacy.com at www.accurate pharmacy.com;
- Caremark Inc. at www.rxrequest.com;
- Clickpharmacy.com at www.clickpharmacy.com;
- CVS Washington Inc. at www.cvs.com;
- drugstore.com at www.drugstore.com;
- Express Pharmacy Services/Eckerd.com at www.eckerd.com;
- familymeds.com at www.familymeds.com;
- Merck-Medco Managed Care LLC at www.merck-medco.com;
- Savon.com at www.Savon.com;
- Tel-Drug Inc./CIGNA at www.teldrug.com;
- VitaRx.com at www.VitaRx.com;
- Walgreens.com Inc. at www.Walgreens.com.

Even with the program, Catizone remains concerned about the ability to order large quantities of Cipro on line.

"More and more people are using the Internet. If there is a run on Cipro over the Internet and there is a shortage, innocent people could be harmed or killed because other people have stockpiled the medications for themselves," he says.

The NABP has been concerned about stockpiling and on-line orders of prescriptions before, but now the issue is more urgent because people are trying to order large quantities of drugs that are needed to treat life-threatening illnesses, he says.

"We have dealt with it before with the 'lifestyle' drugs like Viagra and Propecia. But then, we were worried about individual patients harming themselves and taking medications they maybe should not," he explains. "When you look at it now, if hundreds of people order Cipro on line and deplete the local supply, [and] you or I or our families who need that medication and cannot get it, you are endangering our health."

Although the Atlanta-based Centers for Disease Control and Prevention maintains that it has sufficient antibiotics in its federally authorized pharmaceutical stockpile to provide treatment for anyone exposed to anthrax, stockpiling could still result in distribution worries in the event of a large-scale or multiple-site event, Catizone adds.

Regarding the on-line pharmacies offering generic ciprofloxacin, the FDA warns it is concerned about more than protecting the interests of U.S. pharmaceutical patents. Federal law prohibits the importation of drugs that are not approved in the United States, including foreign versions of U.S.-approved drugs, because they are not subject to FDA evaluation. Drugs ordered via these "rogue" sites could include any of the following:

- The drugs may be contaminated and harmful.
- They could be counterfeit and not contain the advertised drug's active ingredient.
- They could contain the wrong dose.
- They may not be safe and appropriate for the user (in the absence of screening by a health care professional).
- The consumer may not have access to a health care professional if serious side effects occur.
- The consumer may not receive the product at all after sending payment. ■

# Should the public have access to anthrax vaccine?

*High-risk times require closer look at policies*

As this issue of *Medical Ethics Advisor* went to press, the Centers for Disease Control and Prevention (CDC) in Atlanta confirmed 22 cases of anthrax infection — four of them fatal — in the United States.[1] Considering that all of the cases have been civilians working in the private sector — and that most of the cases have been linked to contaminated letters sent through the mail — many are questioning why all available vaccine is reserved for the Department of Defense and use of the anthrax vaccine is still solely restricted to members of the military.

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"When the risk is high, we must re-evaluate our position about making vaccines available to the

public," **Mohammad N. Akhter**, MD, MPH, executive director of the American Public Health Association told members of the Senate Committee on Health, Education, Labor and Pensions during testimony on Oct. 9. Akhter asked that a national committee of experts from the medical, scientific, and intelligence communities be formed to evaluate the risks and benefits of providing both anthrax and smallpox vaccine available to the population at large. Because antibiotic treatment for pulmonary anthrax infection is less effective once symptoms have appeared, it is essential that a vaccine be part of public health preparedness for a large-scale bioterrorist attack, Akhter contends.

But he is not suggesting that current stockpiles of the vaccine, now reserved for military personnel, be made available to vaccinate civilians, he clarifies. In fact, until a newer vaccine is developed, debate about vaccinating civilians is a moot point. "First, the vaccine takes about a month to become effective, and it takes about a year to complete the course of treatment," Akhter explains. The vaccine must be given in six separate shots over the course of 18 months, which is not practical for vaccinating large numbers of the public.

Plus, significant questions remain about the safety of the existing anthrax vaccine, says **David C. Straus**, MD, a professor of microbiology and immunology at Texas Tech University Health Sciences Center in Lubbock.

There is only one manufacturer in the United States — BioPort Inc. of Lansing, MI — authorized to make the vaccine. But citing deficiencies in the company's manufacturing and quality control processes, the Food and Drug Administration (FDA) has refused to allow BioPort to produce new vaccine for the past 3½ years. The Department of Defense, currently BioPort's only customer, wants to buy enough vaccine to inoculate all 2.4 million active and reserve military personnel. However, it still cannot obtain enough vaccine to do so.

The vaccine also has never been approved by the FDA as a measure for preventing inhalation anthrax — the most deadly form of the disease. It has only been demonstrated to be effective at preventing cutaneous anthrax. "You would never use this vaccine to vaccinate everyone in the country," Straus says. "First of all, not everyone in the country is going to come into contact with this stuff. The vaccine still doesn't have FDA approval, and there is not enough of it." Following allegations (never clinically proven) that the anthrax vaccination was linked to the development of Gulf War Syndrome, several active-duty military personnel have faced discipline and court-martial rather than agree to take the vaccine, he adds. "I have not seen clear discussion one way or the other about how safe and effective this vaccine is," Straus says. "The best thing to do is what they are doing now, treat people with antibiotics who they know have been exposed, or think there is a strong likelihood they have been exposed."

Secretary of Health and Human Services Tommy Thompson indicated that two-thirds of his department's requested $1.5 billion to combat bioterrorism will be designated to fund development of new antibiotics and vaccines. Once a suitable vaccine is developed, it should be targeted to civilians who are at risk, as well as military personnel, adds Akhter.

"We know of many situations now in which people are more likely to be exposed, postal workers and mail sorters, obviously," he says. "Also, people who work in labs and people who do investigations of these cases, certainly, they should be candidates to be vaccinated — not just the military."

**SOURCES**

- **Mohammed Akhter**, 800 I St., N.W., Washington, DC 20001.
- **David C. Straus,** 3601 4th St., Lubbock, TX 79430.

### *Reference*

1. Centers for Disease Control and Prevention. Update: Investigation of Bioterrorism-Related Anthrax and Adverse Events from Antimicrobial Prophylaxis. *MMWR* 2001; 50:973-976. ■

# During disasters, how much info should be told?

*Inaccurate information can lead to panic*

At the height of the discovery of anthrax cases in Washington, DC, a hospital public relations staff member created a stir by reporting to the news media that one of the people exposed to the bacteria at Senate Majority Leader Tom Daschle's office was a newspaper reporter who had only been in the hallway outside the senator's suite.

The report turned out to be untrue, but the damage had been done. People in the Capitol

area panicked — believing that a person had been infected simply by passing by a room in which the bacteria had been discovered.

The situation is representative of the problems that can occur when organizations haven't developed clear plans about communicating with the public during crisis situations, says **Philip S. Cogan**, a disaster and crisis management expert and executive vice president of Bernstein Communications Inc. in Springfield, VA.

"The *Washington Post* reported that while it was true the woman was a reporter, she had never even been in that building," Cogan says. "When someone at the hospital asked her, she stated she was a reporter who worked on Capitol Hill. She had never in her career been in the building. The PR person pieced information together from what had been given to him."



In the never-ending quest to satisfy the "24-hour news cycle," hospitals can get caught up in the media frenzy for "updates" and "the latest information" and lose sight of the purpose of sharing information with the public, he says.

"A lot of information provided sometimes appears to be information for information's sake," Cogan explains. "You need to follow a principle that journalists were taught a long time ago: Give people information they can use."

People charged with providing information to the public in crises need to go a step beyond ensuring that the information is factually correct, he says. The public is entitled to information it needs to take steps to protect itself. It is not, however, entitled to any available information, all of the time. "I think they need to ask themselves, 'Is providing this information going to help? Is it going to be information that people can base decisions upon after they analyze the information? Or is it going to contribute to the problem? Is it just going to lead to more questions?'"

During crisis situations, it is important that the public hear correct and consistent information, says **Mohammed Akhter**, MD, MPH, executive director of the American Public Health Association in Washington, DC. "We have seen with the anthrax cases how multiple people were providing information: the Justice Department was saying one thing, the Centers for Disease Control was saying something else, and the local health department was saying another thing.

"As a result, a certain level of mistrust developed in the community and the country," he says.

That kind of vague distrust results from "cognitive dissonance," says Cogan. "Basically, if you give people information that is variant with other information that they receive, they are left with trying to decide what to believe. And that only results in a population that is confused, upset, and maybe even angry."

Medical information providers especially need to realize that they are not islands, even when they are a primary focus in a disaster situation. They are providing information in concert with other health care providers, other hospitals, and government officials.

"All of these other entities are capable of either supporting or undermining the information that you are providing," he explains. "The health care system needs to look at coordinating information activities with governments and among itself, rather than trying to go it alone."

Akhter recommends electing a single voice to deliver updates to the public. He served as state health director for Missouri in the 1980s and as health commissioner for the city of Washington, DC. During his tenure in the nation's capital, he had to contend with contamination of part of the city's water supply. "I had to order that water be boiled for a certain number of people living in this area," he recalls. "I had to talk to the public every morning and every evening: what we were doing, when the results would come back, and when we would make a decision about when they could stop boiling the water. It was very important for people to get information from one source only."

When information comes from a single, medically qualified source, the public knows that it can trust the information, and people don't hear conflicting information that is confusing, he says.

However, having one source of information is often not feasible or practical, especially during a national disaster such as the recent terrorist attacks, Cogan says.

"People in Alabama or California are not going to be seeking reassurance from some official in Washington, DC. They want reassurance from their local public health director, their local hospital administrator, probably even more so from their private physician," he says.

The key is for all sources to speak together, providing information that conforms with what other officials are saying, he says. "When discrepancies exist, it is not necessarily because someone is wrong, but because they are out of sync. A hospital administrator at one facility may give out

information that may have been accurate at a certain point in time, but because they are not linked into a system, it appears to be at variance with something that later is true. Discrepancies also do not always reflect that a certain organization does not know what it is doing, only that it is not working together with other organizations."

Cogan recommends planning for a "joint information center," where representatives from all involved entities will get together to coordinate the release of information. "You all have access to phones and ties back to the original organizations and, when you speak, you speak together and are able to synchronize what the known facts are at particular points in time."

Coordinating the release of information to the public also removes some of the pressure to speculate or predict or otherwise make vague statements that can be damaging later, Cogan adds. "Reporters will always want you to speculate, and deal with hypotheticals. Never make assumptions and never deal in hypotheticals."

If only a limited amount of information is known at a particular time, the communicator has a responsibility to say that he or she has no more information to share.

"Your responsibility is not to intentionally hide information that can be useful, but on the other hand, to not simply provide information in the hopes that the public can make sense out of something the experts are having trouble making sense out of," Cogan says.

Establishing set times for providing information updates also helps alleviate pressure to feed the news cycle, says Akhter. "You need to communicate with the public on a regular, ongoing basis — not a sporadic thing. During the water crisis, I gave updates each day, once in the morning and once in the evening." It's important to give some kind of update, even when there is not much to report, he adds. "If you don't give out some kind of information, that is when the rumors take over."

You have to go out and regularly speak to the public, even to say, "We don't have anything new to report, we just wanted to let you know, we haven't forgotten about you," Cogan agrees. ■

### SOURCES

- **Mohammed Akhter**, 800 I St., N.W., Washington, DC 20001.
- **Philip Cogan,** Bernstein Communications Inc., 6513 Summerton Way, Springfield, VA 22150-1165.

# HHS reaches deal with Bayer on Cipro

*Price lowered, but still monopolized*

Following attacks with anthrax-laced letters in three U.S. cities, resulting in four deaths and confirmed infection in 22 people, demand for the popular antibiotic Cipro soared through the roof, sparking calls for the government to intervene and allow for generic production of ciprofloxacin to meet crisis demand.

However, an 11th-hour deal between the U.S. Department of Health and Human Services (HHS) and West Haven, CT-based Bayer AG will allow the pharmaceutical manufacturer to remain the nation's sole legitimate supplier of the drug.

Under the agreement, signed Oct. 24, HHS will pay Bayer 95 cents per tablet (down from a previously discounted rate of $1.77 per tablet) for a total initial order of 100 million tablets to be shipped by year's end. The government will have the option to buy 200 million more tablets at the newly discounted price. And Bayer will donate 200 million tablets upfront to give to emergency workers and those at high risk for contracting infection. In return, HHS will not exercise its authority to commandeer Bayer's patent on ciprofloxacin (which expires in 2003) to allow generic production.

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"I commend Bayer Corp. for its ongoing efforts to ensure a fully adequate supply of this valuable product. This agreement means that a much larger supply of this important pharmaceutical product will be available if needed," HHS Secretary **Tommy G. Thompson** said, announcing the settlement.

But, several consumer advocate groups charge that the agreement sells out the American public by accepting a still-inflated price for the antibiotics and by not guaranteeing adequate supplies of the drug in the event of a large-scale anthrax exposure.

"This deal puts Americans at risk so Bayer can avoid competition," states **Tim Fuller**, founder of the Stop Patient Abuse Now (SPAN) Coalition, a group of 110 senior and consumer advocacy groups established to ensure greater access to affordable medications. "At some point, consumers and taxpayers are going to demand accountability for the misfeasance at

the Department of Health and Human Services that is putting them at risk."

The 300 million tablets are not enough to ensure that the majority of the 350 million U.S. citizens would have access to a full course of the medication, Fuller states. Most infected patients must take a 60-day regimen of the antibiotics. Allowing generic production, which the government is allowed to do in crisis situations, would allow the five other pharmaceutical companies with FDA approval to make ciprofloxacin to increase the nation's supply much more quickly.

Prior to the anthrax attacks in September and October, Bayer was under fire already from consumer groups — and under investigation by the Federal Trade Commission — for a 1997 agreement to pay three of its competitors, Barr Laboratories, Rugby, and Hoechst-Marion Roussel, millions of dollars to drop challenges to Bayer's patent on Cipro and to not pursue applications to produce generic ciprofloxacin.

On Oct. 25, the Washington, DC-based Prescription Access Litigation (PAL) Project filed suit in the Eastern District of New York asking the court to set aside the agreement, which PAL claimed, had resulted in payments to the companies that totaled $200 million.

Bayer's Cipro is the best-selling antibiotic worldwide and has been for eight consecutive years. In 1999, Cipro was the 11th most prescribed drug in the United states and ranked 20th in total U.S. sales, with gross sales of $1.4 billion.

Such actions are not unique to Bayer and are not unusual in the pharmaceutical industry, says **David Webster**, an expert on pricing issues in the pharmaceutical industry and president of the Webster Consulting Group in Bethlehem, PA.

"It is a common pharmaceutical industry practice, and the [Federal Trade Commission] has actually opened several investigations into agreements of this kind. For example, Schering Plough has been another target," Webster says. "Many companies have been investigated for this, though I don't know of any convictions yet."

Essentially, the drug companies are exploiting several legal "loopholes" that allow them to engage in what many consumer advocates consider to be antitrust behavior, he adds. "There are a couple of regulations that make it easy for them to do this, and it is not really against the law."

First, the law requires that a company seeking to manufacture a generic version of a patented drug, must file an application with the FDA. (Frequently, the second company is applying to make a compound that functions the same as the patented material, but differs in chemical makeup in a minor way, he says.) The holder of the patent for the original drug often sues that company immediately.

"The law says that whenever there is a lawsuit, there is an immediate 30-month hold put on the generic, unless the litigation is resolved," Webster explains.

If the original manufacturer feels it may lose the suit, it may work out a deal with the other company, which wants to avoid the expense of lengthy litigation, he explains. The original manufacturer remains the only supplier of a particular drug and the second company is paid a certain amount of money not to go forward. "It is a win-win for the generic and the pharmaceutical company, but it is often a 'lose' for the consumer."

"There is another loophole that allows the first generic on the market 180 days of exclusivity from the day they go on the market," Webster adds. "If the original pharmaceutical company can delay when the filer goes on the market, they have essentially extended the life of their patent."

Instead of reaching the agreement with Bayer, HHS had a number of options, Webster explains.

One, the agency could have "broken" Bayer's patent on Cipro and allowed other companies to produce ciprofloxacin. Federal law allows the government to do this in certain situations.

"But once they break the patent, they are required to compensate the patent holder and they were concerned about the litigation and the consequences of that clause," he says. "I think members of Congress were considering legislation that would absent them from that component of the law, but that would have been extremely controversial, costly, and time-consuming."

Two, the government could have used what is known as "compulsory licensing" to commandeer Bayer's patent and allow other manufacturer's limited rights to produce Cipro, or the government could allow importation of generic medications from abroad, Webster says.

"Buying it internationally might have been their fastest option," he says. "There are four or

## SOURCES

- **Tim Fuller**, 733 15th St. N.W., Suite 437, Washington, DC 20005.
- **David Webster**, 1525 Valley Center Parkway, Suite 130, Bethlehem, PA 18017.

five manufacturers who are lined up and approved by the FDA to produce ciprofloxacin once the patent expires in 2003. They could have used compulsory licensing to grant them the power to begin producing immediately. But it would have taken them a month or two to get up and running and produce significant quantities. If they bought it on the open market, it would have been a little quicker," notes Webster.

There's no guarantee that the other options would have resulted in better pricing, he says. "Each party has their own interests, those competing against Bayer would have benefited greatly if the patent had been broken. Whoever got the generic award would have made a lot of money." The current deal was a fairly creative strategy on the part of HHS to get more price concessions on a supply of the drug they knew they could get right away, he says.

"They backed Bayer into a corner," Webster says. "Bayer didn't want to get into a situation where, if the patent was broken, then, eventually, they would have to come back and sue the U.S. government for damages for seizing the patent. This would not be great public relations in a national crisis."

Government purchases were already getting enormous discounts on Cipro ($1.77 per tablet compared to $4 per tablet retail in some markets), he continues. And there can be enormous consequences in terms of drug availability and research if patents are not honored and protected, he says.

"Essentially, the incentives for pharmaceutical companies and researchers to conduct the research go down a great deal," he says. "Bayer, for example, has very few other drugs coming out in their pipeline in the next couple of years. They need the money [from Cipro] to fund their research and development of new medications."

### *Should drug companies make a profit?*

The key ethical issue comes down to a debate that goes beyond just the pharmaceutical industry, Webster says. "You'll hear a lot of rhetoric about 'Bayer is capitalizing on a national crisis and it is all going into their pockets.' I know many physicians have the overall opinion that drug companies 'make a profit off the suffering of others. They question all sorts of practices with these companies that we would never question with a computer company or someone who makes automobile tires."

For example, many critics complain about the amount of money drug makers spend on advertising, lobbying of government officials, compensation for top executives, etc.

"Other industries do the same thing without question," he adds. "I don't think it is right or wrong. But I think it needs to be part of the debate about health care in this country. Are pharmaceuticals different? Or are they like any other business in the country? Some people think access to good health care is a fundamental right, while others think "gold-plated" medical care is a luxury, like a Jaguar, that citizens should pay for, he says. "That is a question that we, as a society, have yet to address." ■

## Protecting the uninsured: Is cost-shifting unethical?

*Highest charges usually for those unable to pay*

As hospitals and physicians continue to get squeezed between steeply discounted contract rates from managed health plans and declining payments from government payers, a disturbing new phenomenon is emerging in the U.S. health care system. The highest charges are reserved for those least able to pay: the uninsured.

In return for including a hospital or doctor in its list of preferred providers, managed care organizations (MCOs) often insist on deep discounts for their members. In some cases, the difference between an MCO discounted charge and the provider's normal fee can vary as much as 45% in some areas.[1]

Hospitals traditionally make up any losses by charging higher fees to patients covered by traditional fee-for-service plans. However, with most insured Americans now covered by managed health plans, the only group left to cost-shift to is patients without insurance.

"There are essentially no more private insurers that provide indemnity coverage; it is all managed care," explains **Robert I. Field**, MPH, JD, an associate professor and director of the graduate program of health policy at the University of the Sciences in Philadelphia.

"It is similar to what is happening with pharmaceuticals now. If you have insurance, generally, your plan will go through a pharmacy benefit manager who will negotiate discounts. If you are

in Medicaid, Medicaid negotiates discounts. If you are uninsured, there are no negotiated discounts, so you will pay the full price."

For hospitals, it's important to understand the difference between costs and charges, Field adds. In order to make a profit, a charge will be far more than the actual cost of providing the service. But MCOs have usually negotiated discounts that put the fee they will pay at or below cost.

So, if a surgical procedure costs $5,000 and the charge is $ 8,000, a managed health plan that covers an accountant insured through her employer will pay $5,000 for her surgery, minus a small copay from the patient. But an uninsured construction worker receiving the same procedure can be held responsible for the full amount.

Is it ethical for your facility to expect a patient unable to afford health insurance to pay almost twice as much for a procedure as you charge a contracted health plan?

No, say most health policy experts. But because most uninsured patients cannot afford to pay the full charges, hospitals rarely end up collecting any of the money, anyway. And the system of contracted discounts is the only way hospitals and providers can survive in the current market.

"At the basic level, in and of itself, having these contractual relationships are not unethical," says **Matt Weinberg**, MB, a clinical bioethicist who consults for several hospitals in the Philadelphia area. "Without having them, our health care system would be much more financially strapped than it already is — if that's possible."

### *Work with patients unable to pay*

Even if hospitals are unable to recoup costs from poor, uninsured patients, the charges still exist. Fearful of massive medical bills they are unable to pay, uninsured patients often avoid seeking medical care until their condition becomes critical. And many patients don't get needed care at all.

"I think, as far as elective care goes, people are just not getting it," Field says. "And hospitals won't give it. If you need an operation and don't have insurance and can't prove financial need, most hospitals — nonpublic hospitals at least — just won't schedule the procedure." Many hospitals will negotiate their charges, but individual patients probably do not realize this, he adds.

"I do think it is ethical to go to a commercial insurance company and say, 'If you don't have a special deal with us, you are going to have to pay the full charges for this on behalf of your members," Field notes. "It is another thing to go to an individual who has no insurance and ask for four times what the procedure actually costs."

Although they can't be asked to evaluate individual cases, ethics committees should be aware of what the hospital policies are regarding those who are unable to pay the full amount, Weinberg says .

The Joint Commission on Accreditation of Healthcare Organizations requires hospitals to set up ethical standards with regard to billing practices, he notes. "In policies that I have developed, they basically require that you treat the person with respect and that you will work with them," he says. "I have certainly heard of, and been involved in, a few horror cases where someone calls the hospital and says, 'I have this $2 trillion bill that I can't

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**Editorial Questions**

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afford to pay,' and the person on the other end of the line says, 'We don't care, give us the money or we'll come take your house.' It's usually a situation of that particular billing person was having a bad day, not that it is hospital policy."

As long as such situations are the result of individual personnel problems or isolated incidents, they are not really issues for the ethics committee, he says. "If it is a personnel issue, and not a policy or procedure issue, or a dignity issue, then, as an ethicist, I think we ought not to be involved."

## *Physician charges also are an issue*

The real ethical issues lie more with individual physician practices than with hospitals, which because of their mandate to provide emergency care without a guarantee of payment, are more likely to have established ways of negotiating payment with uninsured and underinsured patients, Weinberg says. "The issues tend to arise when the physician won't accept Medicare or Medicaid at all, or will only accept certain levels of coverage from different private payers."

Weinberg was recently involved in resolving a dispute between parents of an uninsured child and a physician who refused to perform a service because the parents could not demonstrate an ability to pay. "A child with a broken leg was seen in a local emergency room," he explains. "The break had to be set with pins. The orthopedic group who normally served the hospital had an outside orthopedic group covering for them. The orthopedist on call came in and set the limb and placed the pins."

A few months later, when the pins needed to be removed, the mother called the orthopedist's office and asked about getting the procedure. Because the parents had recently applied for Medicaid coverage, but did not have the ability to pay for the procedure, the office manager refused to schedule an appointment.

"I think that because physicians go through medical school on taxpayer-subsidized loans, have their internships funded through Medicare, and that medical students and interns are allowed to go into hospitals and learn on people, these things create significant moral obligations to help people who need your specific services, but are unable to pay," Weinberg says.

"Now, if providing a service at a discount, or waiving the charge, presents a significant hardship to your practice, you are certainly not obligated to do it," he adds. "But I think this is an environment where black-and-white rules do not apply."

Physicians cannot simply leave it up to office managers to handle all billing issues without giving them guidelines about when exceptions to payment "rules" can be made. "Where physicians can be morally questionable is when they turn a blind eye to the billing people and don't give them a clear set of guidelines of when to say yes, when to say no, and when to 'come to me' for the judgment call," he says.


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## SOURCES


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# Medical Ethics Advisor™

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# Continuing Medical Education Test

**JULY 2001**

1. Mitochondrial DNA is:
A. found in the nucleus of an oocyte.
B. contained in rodlike structures in the cytoplasm of a body's cells.
C. not inherited from one generation to the next.
D. undetectable in genetic tests.

2. The human "germline" consists of:
A. the group of genes that are inherited in humans from one generation to the next.
B. the bodies protective defenses against cellular defects.
C. the group infectious diseases that affect humans.
D. the genetic information contained in nuclear DNA.

3. Donor compensation models considered in some states:
A. involve tax credits to businesses who employ living organ donors.
B. involve reimbursements for funeral or burial expenses to families of organ donors.
C. would not involve payment directly for organs, but are designed to remove "disincentives" to donation.
D. all of the above

4. Hospital-based palliative care programs:
A. help support and reinforce the delivery of palliative care to all inpatients with serious, chronic or terminal illness.
B. are designed to establish palliative care as a "separate" medical specialty.
C. can take the place of community hospice programs.
D. exist in many urban acute-care hospitals across the nation.

**AUGUST**

5. A database that collects information about a specific surgical procedure: the technique, patient information, complications, and outcomes, is known as:
A. an archive.
B. a registry.
C. a collective.
D. a report.

6. To ensure that living liver and lung-lobe donors are psychologically sound, have not been coerced, and are physically able to donate, it is essential to:
A. set up a process that allows the candidate to be evaluated separately by a social worker, psychiatrist, and surgeon, none of whom are associated with the transplant patient.
B. provide enough time for all clinical and emotional issues to be examined thoroughly.
C. ensure that the donor understands all of the risks the surgery entails.
D. all of the above.

7. A collection of expert essays on the "business of bioethics" appeared in which publication?
A. *The New York Times*
B. *Journal of Clinical Ethics*
C. *The Hastings Center Report*
D. *The Journal of Pain and Symptom Management*

8. The potential benefits of discussing realistic prognosis predictions with terminally ill cancer patients that are mentioned in this issue include:
A. saving money.
B. allowing the patient to prepare his or her family members and make necessary legal arrangements for dependents.
C. discouraging them from making plans to leave the hospital.
D. none of the above

**SEPTEMBER**

9. The proposed Human Cloning Prohibition Act of 2001 would have banned:
A. reproductive cloning only.
B. reproductive and therapeutic cloning.
C. replication of cell lines.
D. none of the above

10. The company that may hold claim to the universal rights to research embryonic stem cells is:
A. Geron Corp.
B. Wicell Research Institute.
C. Wisconsin Alumni Research Foundation.
D. Celera.

11. In developing its guidelines for behavioral health services, Community Hospitals of Indianapolis decided that:
A. treatment methods that were physically nonintrusive should be preferred over methods that are intrusive.
B. treatment methods that affect the individual's sense of identity should not be used.
C. treatment methods that support self-respect are encouraged.
D. all of the above

12. In the *Wendland* case, the California Supreme Court ruled that:
A. life support on an incompetent patient could not be terminated by a conservator without prior written instructions from the patient.
B. life support on an incompetent patient could not be terminated by a conservator unless the patient was brain-dead or in a persistent vegetative state.
C. for patients neither brain dead nor in a persistent vegetative state, but who were minimally conscious, a conservator would need "clear and convincing evidence" that cessation of life support in that circumstance would be the wishes of the patient.
D. none of the above

**OCTOBER**

13. Participants involved in high-risk research projects should be given more compensation than those involved in research that involves no risk or is low risk.
A. True
B. False

14. Factors that should be considered when determining the amount of payment given to participants in research project include:
A. the characteristics of the population being studied (age, low income level, normal access to health care, etc.).
B. the amount of time involved in participating and the effort required by the participant.
C. whether the subject successfully completed the study.
D. A and B.
E. None of the above

15. Physicians who prescribe opioids like OxyContin for management of chronic pain:
A. have an obligation to monitor patients for signs of inappropriate use.
B. should advocate for balanced policies that preserve access for legitimate uses while preventing diversion for abuse.
C. should follow established practice guidelines for use of opioid derivatives.
D. All of the above

16. Ethicists have raised the following concerns about U.S. policy allowing patents on life forms:
A. Issuing patents will restrict scientific progress by impeding the free flow of communication between researchers.
B. The benefits of research will only be available to an elite segment of the population.
C. Patents on life forms are inherently unjust because they are creations of nature, not of man.
D. All of the above
E. None of the above

**NOVEMBER**

17. Ethicists can play a role in educating providers and the community about bioterrorist events by:
A. conducting seminars.
B. allaying fears.
C. coordinating vaccine drives.
D. all of the above

18. According to a legal opinion issued by the Texas Attorney General:
A. it is against federal law to provide any health care to undocumented immigrants.
B. it is against federal law to provide subsidized, nonemergency care to undocumented immigrants, unless a state legislature passes a law specifically allowing it.
C. federal law allows no exception for subsidized health care services that treat communicable illnesses or emergency medical conditions.
D. publicly funded hospitals cannot offer care to undocumented immigrants, even if they are able to pay the bill.

19. The American Nurses Association:
A. encourages nurses to strike for better pay and benefits.
B. provide guidance for nurses to use collective bargaining and collective actions to improve their workplace and patient care.
C. prohibits members of state nurses' associations from engaging in strikes.
D. none of the above.

20. Physicians who believe that a recently deceased patient is a potential organ donor:
A. should contact a representative of their area organ procurement organization, or a designated requestor at their facility to discuss donation with the patient's family.
B. should immediately approach the patient's family about the possibility of organ donation.
C. should, under no circumstance, discuss donation with the patient's family.
D. all of the above

**DECEMBER**

21. Prescribing ciprofloxacin for patients without any indication they have a resistant bacterial infection can be harmful because:
A. it contributes to a shortage in local supply, and these drugs may be desperately needed by those who are ill.
B. it contributes to development of bacteria that are resistant to the antibiotic, one of the few available to treat bacteria already resistant to older antibiotics.
C. significant side effects have been associated with ciprofloxacin — risk of these side effects may be reasonable in persons with a dangerous infection, but are not in people who are well.
D. all of the above

22. Pharmacists are worried about on-line ordering of prescription drugs because:
A. some of the web sites selling drugs do not ask patients to provide a physician's prescription.
B. previous investigations have found that some products ordered this way are not of the appropriate quality or dosage mandated by the Food and Drug Administration for legal sale in this country.
C. people often order large quantities of popular drugs to "stockpile," which creates a supply shortage in specific areas.
D. all of the above

23. The anthrax vaccine made by BioPort Inc.:
A. is, except for the amount currently held by the military, quarantined because the manufacturing plant has not passed recent FDA inspections.
B. should be made available to the public because it has been deemed safe and effective.
C. has not been proven effective at preventing anthrax infection.
D. has been shown to have a definite link to Gulf War Syndrome.

24. When communicating information to the public during crisis situations, hospital officials should:
A. offer as much information as possible as long as, to the best of their knowledge, the information is accurate at the time.
B. coordinate releases of information with other involved agencies and organizations, release only information that is verifiable and useful to the public, and refuse to engage in speculation.
C. wait until they have useful, verified information before addressing the public at all.
D. all of the above

# Continuing Medical Education Survey

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Please take a moment to answer the following questions to let us know your thoughts on the continuing medical education program. Place an "X" in the appropriate space and **return this page in the envelope with your CME test answer form.** Thank you.

1. Did the program enable you to meet the objectives? Objectives:

- discuss and apply new information about hospital-based approaches to bioethical issues;
- explain developments in the regulatory arena and how they apply to the hospital ethics committee;
- share acquired knowledge of these developments and advances among committee members;
- implement procedures and techniques suggested by experts in the field;
- stay abreast of developments in bioethics and their implications on patient care, risk management, and liability;
- learn how bioethical issues specifically affect physicians, patients, and patient families;
- learn the latest information that can be applied in the committee setting relating to policy and procedure development;
- learn how the roles of different types of health care practitioners are vital to the overall implementation of a viable and useful ethics committee.

☐ Yes ☐ No

2. Did the program meet your expectations as defined in the promotional literature?

☐ Yes ☐ No

3. Were the test questions well-written?

☐ Yes ☐ No

4. Was the test a fair assessment of the learning activity?

☐ Yes ☐ No

5. Were the tests graded and returned efficiently?

☐ Yes ☐ No

6. Did the program help improve your professional effectiveness?

☐ Yes ☐ No

If not, please explain.

_____

_____

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