

would persist even if the overall agreement fell through.

Again the agreement was submitted to the authorities, but what happened next was a surprise. Apotex lawyers informed the FTC that the companies had entered into several oral side agreements that they had kept secret from the authorities. In an e-mail filed with the court that reads as if Sherman sent it to three Apotex executives, he claims that Bristol-Myers said it would still honor certain agreements from the March settlement but not put them in writing because the FTC had previously objected to them. One was Bristol-Myers's promise not to launch its own "authorized generic" clopidogrel to compete with Apotex in 2011. If Sherman's allegations are true, the companies may have violated both federal laws and Bristol-Myers's consent decree. According to Apotex court filings, Sherman "expressly certified to the FTC that these agreements had been made, and how they were negotiated." Bristol-Myers's lawyer, Evan Chesler, disputes Sherman's claims. But in late July, probably because of these allegations, the Department of Justice began its criminal inquiry into the settle-

ment, and FBI agents arrived at Bristol-Myers's New York headquarters with a warrant to search the CEO's office. Days later, the second agreement was rejected by its reviewers.

On the evening of August 7, a beaming Barry Sherman sat in his office at the Apotex complex in a Toronto suburb, talking on the phone. His was the only car in the executive parking area, and Apotex security staff were off duty for a Canadian holiday. No one could have guessed that generic clopidogrel, a billion-dollar drug, would be in pharmacies the next day. "The trucks are rolling," Sherman said in an interview that night, calling it "the biggest launch ever" and revealing that one customer had placed a \$75 million order for the drug. "You'd think everyone would be on our side because we're doing what's right for consumers," Sherman told an Apotex colleague who called his office that night.

Officially, the drug was still under patent, but all the standard protections Hatch-Waxman affords brand-name drug producers had been forfeited by Bristol-Myers and Sanofi in their attempts to settle with Apotex. New York Judge Sidney Stein, who halted

sales of the generic, raised doubts about the entire negotiation by noting that Apotex hadn't convinced him there was any question about the patent's enforceability. The case has cost Bristol-Myers CEO Peter Dolan his job, but Sherman will keep his, all three companies will testify before a grand jury in the criminal case, and they'll meet again in Judge Stein's court when the patent case continues next year.

Meanwhile, other brand-name pharmaceutical companies will probably continue making cash payments to fend off generics. Senators Leahy, Chuck Grassley (R-IA), Charles Schumer (D-NY), and Herb Kohl (D-WI) have proposed outlawing such payments, and the Senate held hearings on the issue in July. As the criminal investigation continues to make headlines, the legislative work will proceed more quietly, but experts say that ultimately, Congressional action may be what's required to stop drug companies from paying off their competition.

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Crisis in the Emergency Department

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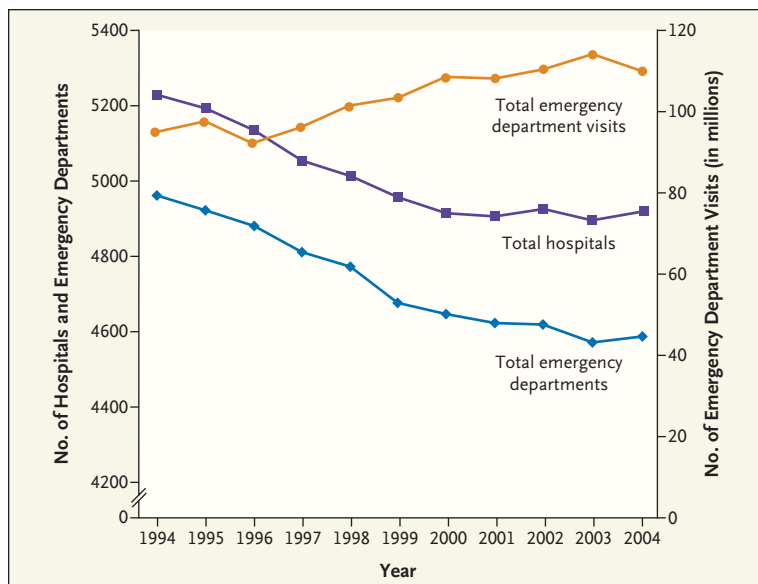
At 2 a.m. on July 27, 1996, I stood in the ambulance bay of Grady Memorial Hospital, awaiting the first of 35 severely injured bombing victims who would be brought to Grady from Atlanta's Olympic Park over the next 2 hours. Although it was a harrowing experience for all involved, the response of Grady's ambulance service, emergency physicians, and trauma surgeons

was so efficient that the hospital had returned to normal operations by 7 a.m.

Much has changed in the decade since the Atlanta bombing. The power and sophistication of terrorist bombings have increased dramatically, but America's emergency and trauma care system has deteriorated to an alarming degree. Today, Grady's trauma service is overflowing, its operating

rooms are always full, and its emergency department is packed with patients. Under such circumstances, it is hard to see how the hospital could manage another bombing on the scale of the Olympic Park event, much less attacks of the magnitude observed in Madrid, London, and Mumbai.

Concerned by these trends, the Josiah Macy Foundation, Congress, and four federal agencies



Trends in Emergency Department Visits, Number of Hospitals, and Number of Emergency Departments in the United States, 1994–2004.

Visits to the emergency department represent about 10% of all outpatient visits in the United States. Data are from the National Health Policy Forum.

asked the Institute of Medicine (IOM) to study the problem. The committee that was assembled to undertake this task, on which I served, was directed to examine the emergency care system in the United States and explore its strengths, limitations, and future challenges. We were also asked to describe a shared vision for the system and recommend strategies for achieving that vision. Our reports, released on June 14, 2006, might be considered the most thorough analysis of this topic since the National Academy of Sciences published “Accidental Death and Disability: The Neglected Disease of Modern Society” 40 years ago.¹

The committee’s three overlapping reports, published by the National Academies Press, are entitled “Hospital Based Emergency Care: At the Breaking Point,” “Emergency Medical Services: At the Crossroads,” and “Pediatric Emergency Care: Growing Pains” (www.iom.edu/emergencycare). Collectively, they describe an over-

burdened system that is rapidly approaching its limits. During the past decade, emergency department visits have increased by 26%, while the number of emergency departments has decreased by 9% and hospitals have closed 198,000 beds (see graph). With more patients needing care and fewer resources to care for them, emergency department crowding was inevitable.

In 2002, a Lewin Group survey determined that 90% of level I trauma centers and hospitals with more than 300 beds were operating at or above capacity.² When a hospital is full, emergency department patients who need inpatient care are “boarded” in exam rooms or hallways until an inpatient bed is available. Boarding ties up space, equipment, and personnel that would otherwise be available to meet the needs of incoming patients. Critically ill patients often wait the longest for admission, because beds in the intensive care unit are in particularly short supply.

When crowding reaches dangerous levels, hospitals often divert inbound ambulances to other facilities. In 2003, diversions occurred more than half a million times — an average of once per minute.³ Diversion may provide a brief respite for a beleaguered staff, but it prolongs ambulance transport times and disrupts established patterns of care. It also creates ripple effects that can compromise access to care throughout a city. Because crowding is rarely limited to a single hospital, one facility’s decision to divert ambulances can prompt others to follow suit. When that happens, a city may experience the health care equivalent of a “rolling black-out.” Everyone’s access to care is affected — the insured and uninsured alike.⁴

The effects of emergency department crowding are exacerbated by a nationwide shortage of nurses. Some hospitals have permanently closed inpatient units because they cannot recruit sufficient staff. Vacancy rates for nursing positions in the emergency department are typically higher than those in the hospital at large, because the work is so stressful.

Physician shortages are another problem. The rising costs of uncompensated care and fear of legal liability for treating high-risk patients have led more surgical specialists to opt out of taking emergency department calls.⁵ Gaps in specialist coverage increase the frequency of ambulance diversion, because hospitals cannot accept certain types of patients if no specialist is available to treat them.

Economic forces underlie these trends. When Congress enacted the Emergency Medical Treatment and Labor Act (EMTALA) in 1986, everyone in the United States ac-



quired a legal right to emergency care. But no funding was provided to pay for it. Not only did this unfunded mandate contribute to the closure of numerous emergency departments and trauma centers, it also created a perverse incentive for hospitals to tolerate emergency department crowding and divert ambulances while continuing to accept elective admissions. Rather than improving access to emergency care, EMTALA diminished it.

These observations aren't new. They've been documented for years by groups as diverse as the Government Accountability Office, the American College of Emergency Physicians, the American College of Surgeons, the American Hospital Association, the Center for Studying Health System Change, the National Health Policy Forum, and the popular press. Five years ago, *U.S. News and World Report* published a cover story entitled "Crisis in the ER: Turnaways and Delays are a Surefire Recipe for Disaster." The date of the issue was September 10, 2001.

Instead of taking decisive ac-

tion to address these concerns, the federal government has largely ignored them. Oversight of emergency and trauma care at the federal level is scattered across three departments (Health and Human Services [DHHS], Transportation, and Homeland Security). Highly capable people work in these agencies, but they lack the authority to reset priorities.

Money is not the problem. Federal spending on bioterrorism and emergency preparedness in DHHS increased from \$237 million in fiscal year 2000 to \$9.6 billion in fiscal year 2006. During the same period, Congress eliminated the Trauma–Emergency Medical Services System program at DHHS. There are currently 52 Centers for Public Health Preparedness with federal funding to address various aspects of bioterrorism, but not one federally funded center focuses on the civilian consequences of terrorist bombings. This is ironic, because explosives are by far the most common instrument of terrorism worldwide.

By definition, "mass casualty events" produce mass casualties. But only 4% of the first-responder funding from the Department of Homeland Security in 2002 and

2003 was directed to emergency medical services. In the upside-down world of federal decision making, even the modestly funded but highly effective Emergency Medical Services for Children program, jointly administered by the Health Resources and Services Administration at DHHS and the Department of Transportation's National Highway Traffic Safety Administration, was considered for elimination.

In its reports, the IOM committee makes several recommendations to reverse these trends. Among them, five stand out. The committee calls on the federal government to consolidate functions related to emergency care into a single lead agency based at DHHS. This move would increase accountability, minimize duplication of effort, and fill important gaps in federal support. A focused examination of needs would also advance research on emergency care, which is an orphan in the byzantine world of federal research agencies.

State governments should promote the regionalization of prehospital and hospital-based emergency and trauma care. Such interinstitutional cooperation would ensure that patients get to the right hospital at the right time and help hospitals preserve emergency department coverage by on-call specialists.

The committee calls on hospitals to end the boarding of admitted patients in emergency departments and the diversion of ambulances, except in extreme cases, such as community-wide disasters. Hospitals can achieve this goal by adopting operations-management techniques and related strategies to enhance efficiency and improve patient flow. The committee recognizes that merely exhorting administrators

to do the right thing won't be sufficient if such action will harm the hospital's bottom line. To spur needed change, the Center for Medicare and Medicaid Services must create incentives for hospitals to move admitted patients promptly to inpatient units. The Joint Commission on Accreditation of Healthcare Organizations can help by reinstating strong standards that discourage boarding and emergency department crowding.

Strengthening disaster response is a key priority, regardless of whether the event is caused by a natural catastrophe, terrorism, or an emerging infectious disease. The committee believes that the best way to prepare for disasters is to create an emergency and

trauma care system that functions effectively on a day-to-day basis. Key aspects of disaster response should be addressed regularly in the training, continuing education, and credentialing of emergency care professionals.

When your life is on the line, you want your doctor — not your ambulance — to go the extra mile. To replace the fragmented, overwhelmed system we have today, the IOM envisions a coordinated, regionalized, and accountable emergency care system that is capable of delivering lifesaving treatment to all in need. It is up to Congress, the federal government, and all of us to make this vision a reality.

An interview with Dr. Kellermann can be heard at www.nejm.org.

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FOCUS ON RESEARCH

The Continuing Risk of Transfusion-Transmitted Infections

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Related article, p. 1331

In 2002, as mosquitoes carried West Nile virus across the United States, infecting 4200 people, 23 confirmed cases of transfusion-transmitted infection and 7 related deaths were reported.¹ This was a dramatic demonstration that an emerging agent can threaten the safety of the blood supply. Because the virus's incubation period is usually 3 to 15 days and transmission by transfusion stood out against the background of a mosquito-borne epidemic, these transmissions were recognized quickly, nucleic acid-amplification technology was adapted for the detection of the virus, and the Food and Drug Administration (FDA) and Health Canada mandated the screening of donated blood for West Nile virus nucleic acid.

Thanks to many blood-safety interventions introduced in the United States between 1984 and 2004, the overall risk of transfusion-transmitted infections has become exceedingly small (see graph).² Currently, blood donors are questioned about risk factors for several parenterally or sexually transmitted viruses, including hepatitis B and C viruses (HBV and HCV, respectively), human immunodeficiency virus types 1 and 2 (HIV-1 and -2, respectively), and human T-cell lymphotropic virus types I and II (HTLV-I and -II, respectively), and blood is screened for indicators of infection. Donors are also asked about risk factors for malaria, babesiosis, and Chagas' disease. Blood intended for transfusion into patients who are at increased risk for cyto-

megalovirus (CMV) disease is tested for CMV antibody or undergoes leukocyte reduction, since CMV resides in the white cells.

Since March 2004, platelet components in the United States have been screened for the presence of bacteria, because as many as 1 in 3000 random-donor platelet concentrates had been reported to be contaminated by a wide variety of both gram-positive and gram-negative bacteria, and bacterial sepsis had emerged as the most common transfusion-transmitted infection. Deaths from bacterial sepsis have continued to be reported, both because red-cell units are not screened and because the available methods for screening platelets are suboptimal. Between 2001 and 2003, an average of 11.7 deaths from bacterial sepsis per