

in application of the accelerated-approval pathway and clarified the use of an intermediate clinical end point as a basis for accelerated approval. In Table 2, we compare the qualifying criteria and features of each of the four expedited programs.

The FDA has recently released draft guidance on expedited programs for drugs for serious conditions, including the breakthrough-therapy designation.¹ The draft guidance outlines the qualifying criteria and the process for requesting a breakthrough-therapy designation for investigational

drugs, and it describes features of the program that are intended to streamline drug development for highly promising agents.

The breakthrough-therapy designation program is of great interest to patients and patient advocates. Because designations are given to drugs in development, it will be some time before the program's effect on access to important therapies can be assessed. This program may represent the initiation of a new paradigm for investigational drugs undergoing development in a setting of extensive mechanistic understand-

ing of disease pathogenesis. As the pace of scientific discovery continues to increase, drug-development pathways will need to evolve in parallel.

Disclosure forms provided by the authors are available with the full text of this article at [NEJM.org](http://www.nejm.org).

From the Center for Drug Evaluation and Research, Food and Drug Administration, Silver Spring, MD.

1. Guidance for industry: expedited programs for serious conditions — drugs and biologics. Silver Spring, MD: Food and Drug Administration (<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>).

DOI: 10.1056/NEJMp1311439

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Dead Man Walking

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“**S**hocked” wouldn’t be accurate, since we were accustomed to our uninsured patients’ receiving inadequate medical care. “Saddened” wasn’t right, either, only pecking at the edge of our response. And “disheartened” just smacked of victimhood. After hearing this story, we were neither shocked nor saddened nor disheartened. We were simply appalled.

We met Tommy Davis in our hospital’s clinic for indigent persons in March 2013 (the name and date have been changed to protect the patient’s privacy). He and his wife had been chronically uninsured despite working full-time jobs and were now facing disastrous consequences.

The week before this appointment, Mr. Davis had come to our emergency department with abdominal pain and obstipation. His examination, laboratory tests, and CT scan had cost him \$10,000 (his entire life savings), and at evening’s end he’d been sent home with a diagnosis of metastatic colon cancer.

The year before, he’d had sim-

ilar symptoms and visited a primary care physician, who had taken a cursory history, told Mr. Davis he’d need insurance to be adequately evaluated, and billed him \$200 for the appointment. Since Mr. Davis was poor and ineligible for Kentucky Medicaid, however, he’d simply used enemas until he was unable to defecate. By the time of his emergency department evaluation, he had a fully obstructed colon and widespread disease and chose to forgo treatment.

Mr. Davis had had an inkling that something was awry, but he’d been unable to pay for an evaluation. As his wife sobbed next to him in our examination room, he recounted his months of weight loss, the unbearable pain of his bowel movements, and his gnawing suspicion that he had cancer. “If we’d found it sooner,” he contended, “it would have made a difference. But now I’m just a dead man walking.”

For many of our patients, poverty alone limits access to care. We recently saw a man with AIDS and a full-body rash who couldn’t

afford bus fare to a dermatology appointment. We sometimes pay for our patients’ medications because they are unable to cover even a \$4 copayment. But a fair number of our patients — the medical “have-nots” — are denied basic services simply because they lack insurance, and our country’s response to this problem has, at times, seemed toothless.

In our clinic, uninsured patients frequently find necessary care unobtainable. An obese 60-year-old woman with symptoms and signs of congestive heart failure was recently evaluated in the clinic. She couldn’t afford the echocardiogram and evaluation for ischemic heart disease that most internists would have ordered, so furosemide treatment was initiated and adjusted to relieve her symptoms. This past spring, our colleagues saw a woman with a newly discovered lung nodule that was highly suspicious for cancer. She was referred to a thoracic surgeon, but he insisted that she first have a PET scan — a test for which she couldn’t possibly pay.

However unconscionable we may find the story of Mr. Davis, a U.S. citizen who will die because he was uninsured, the literature suggests that it's a common tale. A 2009 study revealed a direct correlation between lack of insurance and increased mortality and suggested that nearly 45,000 American adults die each year because they have no medical coverage.¹ And although we can't confidently argue that Mr. Davis would have survived had he been insured, research suggests that possibility; formerly uninsured adults given access to Oregon Medicaid were more likely than those who remained uninsured to have a usual place of care and a personal physician, to attend outpatient medical visits, and to receive recommended preventive care.² Had Mr. Davis been insured, he might well have been offered timely and appropriate screening for colorectal cancer, and his abdominal pain and obstruction would surely have been urgently evaluated.

Elected officials bear a great deal of blame for the appalling vulnerability of the 22% of American adults who currently lack insurance. The Affordable Care Act (ACA) — the only legitimate legislative attempt to provide near-universal health coverage — remains under attack from some members of Congress, and our own two senators argue that enhancing marketplace competition and enacting tort reform will provide security enough for our nation's poor.

In discussing (and grieving over) what has happened to Mr. Davis and our many clinic patients whose health suffers for lack of insurance, we have considered our own obligations. As some congresspeople attempt to defund Obamacare, and as some states' governors and attorneys general

deliberate over whether to implement health insurance exchanges and expand Medicaid eligibility, how can we as physicians ensure that the needs of patients like Mr. Davis are met?

First, we can honor our fundamental professional duty to help. Some have argued that the onus for providing access to health care rests on society at large rather than on individual physicians,³ yet the Hippocratic Oath compels us to treat the sick according to our ability and judgment and to keep them from harm and injustice. Even as we continue to hope for and work toward a future in which all Americans have health insurance, we believe it's our individual professional responsibility to treat people in need.

Second, we can familiarize ourselves with legislative details and educate our patients about proposed health care reforms. During our appointment with Mr. Davis, he worried aloud that under the ACA, "the government would tax him for not having insurance." He was unaware (as many of our poor and uninsured patients may be) that under that law's final rule, he and his family would meet the eligibility criteria for Medicaid and hence have access to comprehensive and affordable care.

Finally, we can pressure our professional organizations to demand health care for all. The American College of Physicians, the American Medical Association, and the Society of General Internal Medicine have endorsed the principle of universal health care coverage yet have generally remained silent during years of political debate. Lack of insurance can be lethal, and we believe our professional community should treat inaccessible coverage as a public health catastrophe and stand behind people who are at risk.

Seventy percent of our clinic patients have no health insurance, and they are all frighteningly vulnerable; their care is erratic, they are disqualified from receiving certain preventive and screening measures, and their lack of resources prevents them from participating in the medical system. And this is not a community- or state-specific problem. A recent study showed that underinsured patients have higher mortality rates after myocardial infarction,⁴ and it is well documented that our country's uninsured present with later-stage cancers and more poorly controlled chronic diseases than do patients with insurance.⁵ We find it terribly and tragically inhumane that Mr. Davis and tens of thousands of other citizens of this wealthy country will die this year for lack of insurance.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

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This article was published on October 23, 2013, at NEJM.org.

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DOI: 10.1056/NEJMp1312793

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