

# US court rules to allow experimental drugs for dying patients

People dying from a terminal illness have the right to buy experimental drugs from companies before the US Food and Drug Administration (FDA) has approved them, a US federal appeals court ruled in May.

If upheld, the ruling could bring hope to people desperately trying to extend their lives, but it could also shake up the government's drug approval process, legal experts say.

"If it's not overturned, it could have a mind-boggling effect," says Jerry Menikoff, a health law expert at the University of Kansas. "Not allowing access to experimental drugs is the way we get studies done."

Because experimental drugs have not yet been fully evaluated, taking them carries a risk of nasty side effects or even death. The FDA forbids companies from selling these drugs. Some people might be able to access the drugs by enrolling in clinical trials or, in circumstances such as a life-threatening illness, by appealing to companies'

'compassionate use' programs.

The new ruling is the result of a lawsuit filed against the FDA by the advocacy group Abigail Alliance.

Frank Burroughs created the group after his daughter Abigail died in 2001 while trying to enroll in a clinical study of Erbitux, a cancer treatment that has since been approved by the FDA. Burroughs argues that companies should be permitted to sell to terminally ill people drugs that have passed phase 1 trials. "The patients are willing to take on the unseen risks," he says.

A Washington, DC district court dismissed the lawsuit in 2004, but in May, an appeals court agreed with the alliance and sent the case back to the district court.

The FDA can request that the US Supreme Court or the appeals court revisit the decision. As of 23 May, the agency had not yet announced its move.

The ruling could give companies complete control over which terminally ill individuals

receive the drug before approval. It could also eliminate the incentive for people to enroll in clinical studies, effectively slowing down the approval process, legal experts say.

"In the real world, this could create the ultimate nightmare," says Peter Hutt, a partner at the law firm Covington and Burling, and a former head counsel for the FDA. "It might almost eliminate placebo trials. And if a phase 2 shows efficacy, no one would show up to phase 3."

Despite its radical implications, the policy is similar to one that other countries are moving toward. In November 2005, the European Agency for the Evaluation of Medicinal Products set guidelines to help European countries broaden their compassionate use programs and allow easier access to experimental drugs.

"What right do we have to take away a dying patient's last hope?" asks Hutt. "Give them anything they want."

*Emily Waltz, New York*

## Odd epidemic injects shot of doubt about mumps vaccine

At some point last winter, a single person, probably traveling from the UK, brought the viral illness mumps to the US state of Iowa. From that one individual, the disease has spread to more than 3,090 Americans in 13 states, including ones as far away as New York.

The outbreak has left most Americans scratching their heads—if they're lucky enough to have escaped the fevers, headache and swollen glands typical of infection: isn't the mumps vaccine supposed to prevent outbreaks?

The epidemic first cropped up in December, when the Iowa state public health department picked up on a handful of cases. As of 18 May, Iowa had confirmed 1,327 cases, with hundreds more suspected. Most cropped up in college-aged students, and a startling 63% had been vaccinated at least once for the disease.

Experts have long known that the vaccine for mumps—given along with shots for measles and rubella in the so-called MMR vaccine—is one of the weaker childhood jabs. One dose of the mumps vaccine confers about 80% immunity in children and the booster bolsters that to between 90% and 95%. Compare that with measles, which has a 95% efficacy rate after one shot and up to 99% after the booster.

"There's no evidence that the mumps vaccine isn't working as expected," says Patricia Quinlisk, Iowa's state epidemiologist. "But it's not the greatest vaccine. I wish it were more like the



**Mumps' the word:** An unexpected outbreak of the viral illness has spread to 13 US states.

measles shot."

The vaccine strains first used in MMR may have given higher titers in earlier clinical trials because the disease was then still endemic, and conferred a degree of background immunity.

Drug companies have since been trying to improve the vaccine, primarily by switching the mumps strains included in the shot. The latest innovation came last year, when the US Food and Drug Administration approved ProQuad, which combines the MMR vaccine with a shot against chickenpox.

Most people now in college were only required to get one MMR shot before entering elementary school. But after 1991, children in Iowa have been

required to get two doses. In a teleconference with reporters on 19 April, Jane Seward of the US Centers for Disease Control and Prevention said that teenagers who got two doses of the vaccine have been better protected. "That would lead us to believe... that we are getting very good protection from the MMR vaccine," she said.

Epidemiologists say the spread of the virus in a college-aged population isn't surprising. Colleges are full of highly social dorm denizens sharing sodas and swapping spit—the perfect breeding ground for any epidemic. Young Iowans presumably incubated and spread the virus to other states through travel, especially during spring break. The epidemic appears to be winding down, partly due to a targeted vaccination campaign and the end of the college year.

But how the virus got to Iowa remains a puzzle. The strain of mumps circulating in the US, genotype G, is the same one that has caused an epidemic in the UK for two years, which bolsters the popular theory about the origin of the virus. More than 70,000 people in the UK have fallen ill with the disease and unvaccinated UK travelers have started US mumps outbreaks before—most recently, at a summer camp in New York last year.

The epidemic there has been driven by fears that vaccines can lead to autism, despite evidence to the contrary.

*Erika Check, San Francisco*