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By Gail Oskin, AP

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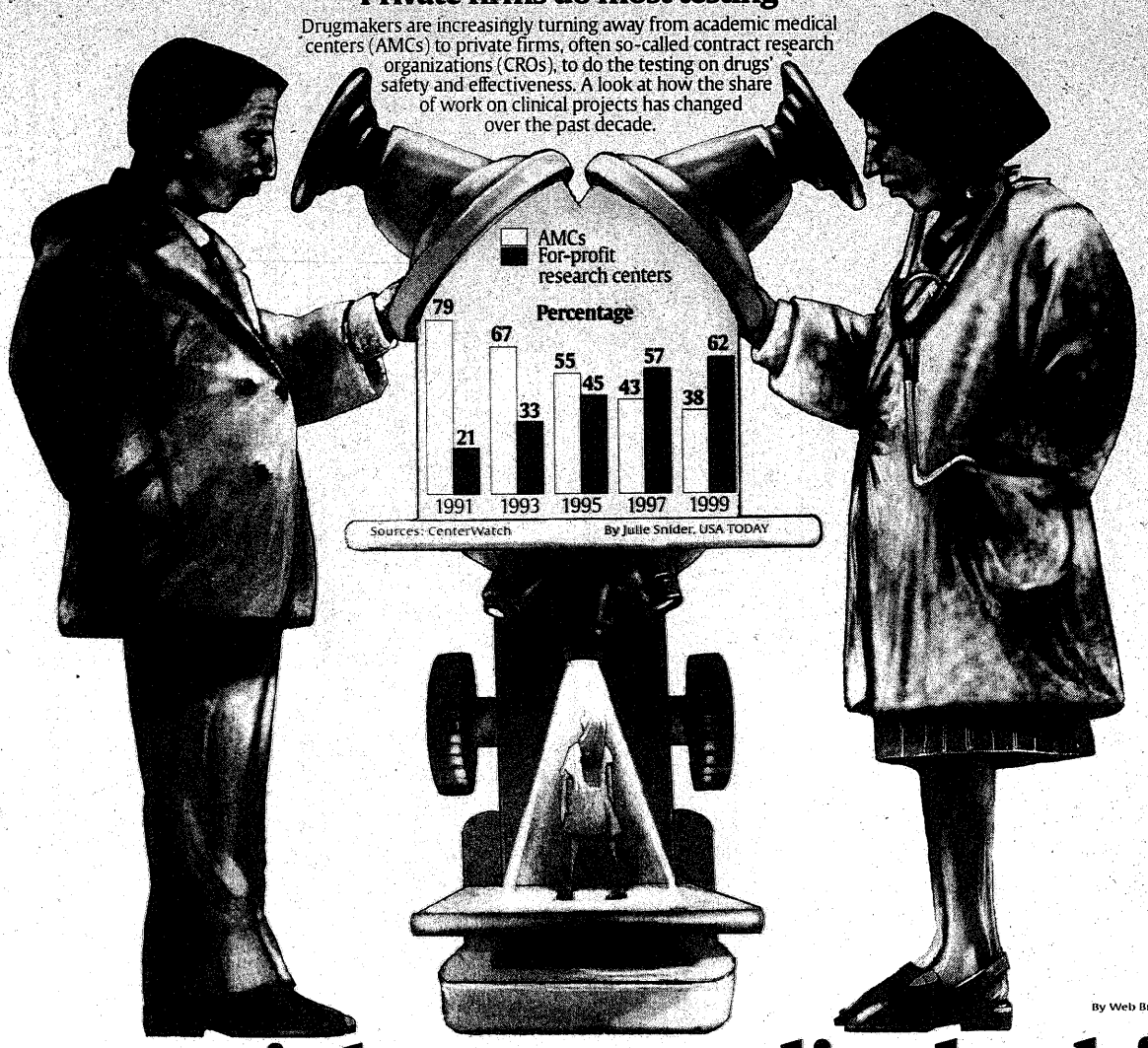
Private firms do most testing

Drugmakers are increasingly turning away from academic medical centers (AMCs) to private firms, often so-called contract research organizations (CROs), to do the testing on drugs' safety and effectiveness. A look at how the share of work on clinical projects has changed over the past decade.



By Web Bryant, USA TODAY

Drug trials vex medical ethics

Academic experts put testing by private companies under a microscope

By Dan Vergano
USA TODAY

In the debate that raged after the death of Jesse Gelsinger, a teenager who died during a gene-transfer study at the University of Pennsylvania, one change went almost unnoticed: The university decided to hire private companies to conduct future human experiments deemed "to involve significant risk."

Penn is not the only one.

A recent report in *The New England Journal of Medicine* noted that drugmakers are turning away from academic medical centers. Instead, they are using contract research organizations (CROs), private companies that now run the majority of the clinical trials used to test drugs' effects before the Food and Drug Administration approves their sale. And not everyone in medicine is happy about the change.

Unburdened by treatment and teaching responsibilities, a CRO often provides a faster, cheaper way to launch a drug study than do medical schools, says Kenneth Getz of CenterWatch, a Boston-based industry watcher. That concerns in clinical trials. Bodenheimer will join federal officials in outlining areas of concern, including CROs.

Adding to worries over CROs' allegiances, researchers have found evidence that funding sources affect research results.

Last year, a Northwestern University study found that studies sponsored by drug companies reported negative results with drugs 5% of the time, vs. 38% in efforts financed by other sources.

Teaching hospitals focus on patient

Billions spent on clinical trials

Nationwide, private spending on clinical trials has expanded rapidly in recent years, from $7.5 billion in 1998 to $9 billion today, according to the Pharmaceutical Research and Manufacturers of America (PhRMA). Regulatory demands for larger experiments designed to ferret out drug side effects and increase medical knowledge drive the spending, industry spokesmen say.

As a result, ads for participants in clinical trials now fill newspapers and radio

Volunteers should ask lots of questions

Patients considering entering a clinical trial should ask their physicians how it will affect their care, says Cynthia McGuire Dunn of the University of Rochester (N.Y.).

"When you volunteer, you're no longer a patient. You're a study participant," she says. "The researcher-subject relationship focuses on answering bigger questions than individual care."

Questions to ask your doctor, she says, include:

- How will my treatment differ from what I would normally get?
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In that case, they would receive the current standard of care for an ailment or, in some cases, a placebo treatment in which the pill they take or the care they get is intentionally designed to have no effect.

The National Institutes of Health Web site offers information about clinical trials at www.clinicaltrials.gov/ct/gui.

of-interest risks that our industry faces," Danna says. "It's a real concern, and researchers, managers and reviewers have to know how to handle it."

Academia's borders blurred

Not even everyone in academia agrees with Bodenheimer.

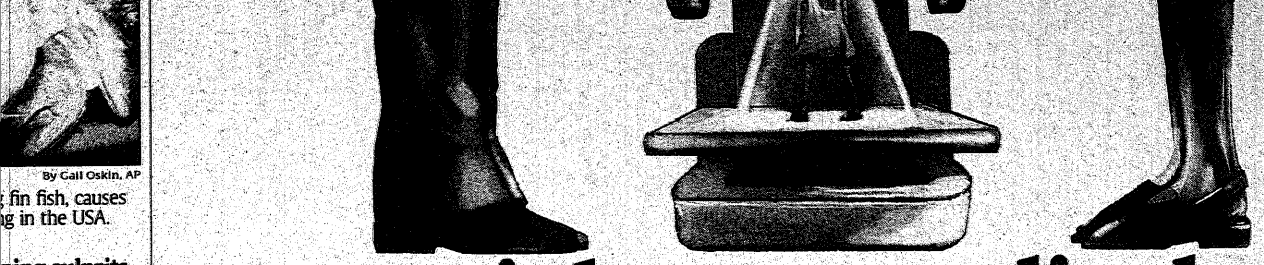
"I think he offers a bit of an incomplete perspective," says Cynthia McGuire Dunn of the University of Rochester (N.Y.), who argues that academic medical centers can compete in attracting clinical trials. Such funding has tripled at her institution since 1996, when Dunn inaugurated a program to certify researchers on the regulatory and ethical issues they face in conducting such studies.

In addition, the largest private research companies have hit hard times in the past year and plan to lay off hundreds of workers, notes Getz, a factor that makes them less of a threat to take over drug research. Attempts by CROs to sell themselves as able to develop a drug from identification to market have not been successful, he adds.

"They can't deliver the hands-on management they've promised, unlike smaller firms," Getz says.

Finally, most CROs simply act as middlemen between companies and the academic researchers who run trials most efficiently, says Bert Spilker of PhRMA. "They're the same academics conducting research either way."

But school officials such as Joseph



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Unburdened by treatment and teaching responsibilities, a CRO often provides a faster, cheaper way to launch a drug study than do medical schools, says Kenneth Getz of CenterWatch, a Boston-based industry watcher. That makes CROs attractive to companies with drugs to test. But critics say that allowing CROs, which work directly for drugmakers, to evaluate those same companies' products sets off alarm bells, considering the CROs are beholden to the companies for future contracts.

"We certainly have to ask whose creatures they are," says Marcia Angell, former editor of *The New England Journal of Medicine*.

Like Thomas Bodenheimer of the University of California at San Francisco, who authored the recent *New England Journal of Medicine* report, Angell fears that some CROs, obligated to a particular company for survival, might bury study results pointing to drug side effects — or initiate studies designed solely to win FDA approval for a drug. Perhaps they would not fully check for risks, endangering people's health when the product hits pharmacy shelves.

Conflict-of-interest concerns

This month, the Department of Health and Human Services plans a conference to discuss conflict-of-interest concerns in clinical trials. Bodenheimer will join federal officials in outlining areas of concern, including CROs.

Adding to worries over CROs' allegiances, researchers have found evidence that funding sources affect research results.

Last year, a Northwestern University study found that studies sponsored by drug companies reported negative results with drugs 5% of the time, vs. 38% in efforts financed by other sources.

Teaching hospitals focus on patient treatment and physician training, along with research, Bodenheimer says. In contrast, private companies exist to make money, period, he says. "CROs need contracts to survive."

And drugs need to run a gantlet of tests in humans to survive the FDA approval process.

After identification, toxicology tests and testing on animals, the makers of a new drug seek the federal government's permission to test it on humans.

Subsequent Phase 1 trials generally test the drug for side effects and safety in humans, not for beneficial effects. In Phase 2 and Phase 3 trials, the drugs are tested in increasing numbers of people, sometimes involving thousands of participants worldwide.

When a company receives approval from the FDA to market a drug, it may commit to Phase 4 studies, designed to measure the drug's side effects in its customers.

In April, the consumer group Public Citizen noted that in the past 10 years, only 13% of the makers of new drugs met their commitments to conduct Phase 4 studies.

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Nationwide, private spending on clinical trials has expanded rapidly in recent years, from $7.5 billion in 1998 to $9 billion today, according to the Pharmaceutical Research and Manufacturers of America (PhRMA). Regulatory demands for larger experiments designed to ferret out drug side effects and increase medical knowledge drive the spending, industry spokesmen say.

As a result, ads for participants in clinical trials now fill newspapers and radio broadcasts. And recently, organizations including the National Cancer Institute have taken measures to increase patient interest, putting a list of trials online. A recent inspector general's report from the Department of Health and Human Services documented instances in which doctors are paid to recruit their own patients into trials in an atmosphere of rushed, possibly dangerous efforts to enroll patients in studies.

And despite the pharmaceutical industry's increases in clinical trial funding, academic medical centers have seen their share of industry money spent on large drug trials drop from 80% in 1991 to less than 40% today, CenterWatch's Getz says.

Bob Danna of Beardsworth Consulting Group, a midsize CRO based in Flemington, N.J., concedes that CROs may face a higher burden of proving their freedom from bias, compared with academic researchers. But Danna, like others, argues that Bodenheimer's health policy report overstates the risk that CROs do bad research.

"We're certainly aware of the conflict-of-interest risks that our industry faces," Danna says. "It's a real concern, and researchers, managers and reviewers have to know how to handle it."

Academia's borders blurred

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But school officials such as Joseph Martin, dean of Harvard Medical School, note that academic institutions can lose some control over their researchers when they start working with CROs.

In April, for example, the FDA sent a warning letter to Tufts University researcher Jeffrey Isner, citing violations in his conduct of a gene therapy trial that included "failure to protect the welfare of subjects." But the letter didn't mention Tufts, naming instead trial sponsors Isner, St. Elizabeth's Hospital in Boston and Vascular Genetics of Durham, N.C.

The last sponsor, a gene therapy firm, was founded in 1997 by Human Genome Sciences Inc., Isner, St. Elizabeth's and Cato Holding, a Durham-based CRO.

"Academia ought to take back some of its share in clinical research," Martin says. "I view the whole responsibility of our institution as going from (lab) bench to bedside." Spurred by a recent debate at Harvard over how large a financial interest researchers may hold in drug companies, he hopes to convene a meeting of major medical institution heads to begin discussing national standards this year.

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SIDS rate twice as high in day-care providers' homes

Parents must make sure babies sleep on back

Medical Center in Washington, D.C. Her report is in *Pediatrics*.

"It's very concerning because these

But 14.7% of deaths were in these settings in her survey of all SIDS incidents in 11 states over 2½ years.

ter-educated whites are most likely to have kids in child care," Moon says.

Infants who usually sleep on their