millions of stars; others are more sparse and diffuse. It's these loose systems that run the highest risk of being torn apart by tidal forces, which arise because the Milky Way's gravity is stronger on one side of the cluster than on the other. Astronomers have suspected that this fate might befall some clusters, but convincing direct evidence was missing.

Now there's definitive proof in data from the Sloan Digital Sky Survey, a large international project to map one-quarter of the sky in exquisite detail (*Science*, 25 May 2001, p. 1472). A team led by Eva Grebel of the Max Planck Institute for Astronomy (MPIA) in Heidelberg, Germany, scrutinized stars near Palomar 5, a sparse globular cluster 75,000 light-years from Earth. On opposite sides of the cluster the astronomers found streams of stars stretching 13,000 light-years from end to end—20 times the apparent width of the full moon. These "tidal tails" form when stars are torn loose from the cluster and then slowly drift away. "It's a very amazing structure," says team member Michael Odenkirchen, also at MPIA. "Nothing like this has ever been seen before." Odenkirchen expects the cluster to disappear completely within 100 million years.

To discover the tails, astronomers had to filter out the countless stars and background galaxies in the field of view that did not match the expected colors and brightnesses of globular cluster members. The finding suggests that many other sparse globulars have been torn apart completely in the past; detecting Palomar 5 in the process of being ripped to pieces was apparently just a lucky catch.

Because the tails more or less delineate the orbit of the parent globular cluster around the Milky Way center—information that's impossible to come by otherwise—the data will help scientists map the distribution of dark matter in the Milky Way, Spergel says: "The tidal tail observations should enable astronomers to measure both the lumpiness of the dark matter and its central density." That kind of information can help scientists rule out or refine models of what dark matter is and how it has shaped the evolution of the universe, he says.

–GOVERT SCHILLING

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CLINICAL TRIALS

Agency Wants to Stop Shopping for Best Deal

Every child knows that if Mom says no, she can always ask Dad. Now, the U.S. Food and Drug Administration (FDA) is worried that clinical researchers might try the same trick: Find a new set of safety officials to approve a study involving human subjects that has been rejected by another panel. To deter such behavior, the government has proposed that researchers be required to tell safety panels about any prior reviews. But last week the biomedical community gave the plan* a mixed reception.

The safety panels—known as Institutional Review Boards (IRBs)—must approve all research involving human subjects. Most academic researchers have no choice but to submit their plans to the IRB at their home institution. But a drug company sponsoring a multisite trial has more options, from submitting plans to multiple boards to employing a private "superboard" to which individual institutions have ceded authority.

The FDA proposal is a response to a 1998 report by the department's inspector general that concluded new procedures were needed

ILLUSTRATION: C. SLAYDEN

to prevent researchers from "IRB shopping" to find a more agreeable review panel. But critics aren't buying FDA's solution. They argue that shopping is rare and that disclosure rules would do little to improve patient protection. The debate "is part of a larger discussion about how to overhaul human subject protection" in the wake of the deaths of several study participants and a government crackdown on informed consent procedures at major research universities, notes Abbey Meyers, president of the National Organization for Rare Disorders in New Fairfield, Connecticut.

Some respondents to FDA's request for comment doubt that shopping is a problem worthy of federal regulation. Officials at drug giant Merck & Co. in West Point, Pennsylvania, for instance, said they could identify only one instance in more than 1500 clinical trials the company has sponsored over the last 5 years where researchers even discussed approaching a second IRB when they were unhappy with a first ruling. Even that case, says company vice president David Blois, occurred only after the first panel imposed legal requirements that boosted study costs. He recommends that FDA delay regulation until more data are available.

But some veteran reviewers say that big companies try to intimidate an IRB if it suggests changes in protocols or consent forms. Barbara Bigby, head of research subject protection at the Scripps Clinic in La Jolla, California, noted that research sponsors "frequently" tell her reviewers that they are the only ones expressing such concern. It's a tactic, she says, that's meant to get the panel to back down. "Yet when we communicate [with other IRBs that have reviewed the proposed study]," she wrote, "we find that our concerns are similar" to theirs.

Commenters also disagreed about who should notify IRBs. Companies nominated investigators, saying they are closest to the studies. But the American Society of Gene Therapy spoke for many researchers and universities in arguing that sponsors should bear the burden, especially in clinical trials that might stretch across hundreds of domestic and foreign sites.

There was more agreement on other issues. Both supporters and critics of disclosure warned that tracking multisite studies could cause paperwork-induced gridlock for researchers, institutions, and IRBs alike—although a Web-based filing system could help. They also worried about a "herd mentality" in which IRBs at large or prestigious research centers would set the pace. Some researchers fear that shoppers could avoid disclosure simply by tweaking their proposals to make them appear novel. There were also questions about how offenders might be punished.

FDA officials are expected to spend several months chewing on the comments before deciding on their next move. In the meantime, the scientific community is already taking some steps in the direction that FDA might be headed. Biomedical researchers report that some IRBs have already begun to ask researchers about prior decisions. And the Association of American Medical Colleges (AAMC), which offered qualified support to disclosure, believes that a new voluntary accreditation program for institutions conducting human research will standardize reviewing practices. That step, says AAMC, would reduce the chances that researchers can get a better deal at the next IRB.

–DAVID MALAKOFF

*www.fda.gov/OHRMS/DOCKETS/98fr/040102a.htm