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Health Issues

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The Food and Drug Administration (FDA) is moving to broaden access to experimental drugs for people with serious illnesses, with efforts that would represent a middle ground in the emotional debate over when unproven treatments should be available to patients with no other options, says the Wall Street Journal.

Two proposals by the FDA:

- Laying out a formal pathway for small groups and individual patients to get access to unapproved drugs, clarifying the FDA's standards and making the process easier.
- Defining more clearly specific circumstances under which patients could be charged for an unapproved drug -- without allowing companies and researchers to make a profit -- which aren't completely clear in the current regulation.

The FDA changes wouldn't go nearly as far as some want, however. A plan pushed by the Abigail Alliance for Better Access to Developmental Drugs and the Washington Legal Foundation, two nonprofits, favor a pathway that would let drug makers sell their experimental medicines at a profit, though with some restrictions, after they had shown potential efficacy in even a small number of patients.

But some researchers worry that patients may actually expose themselves to more risk by taking unproven drugs. The National Coalition for Cancer Survivorship and the American Society of Clinical Oncology have filed a petition that presses the agency to clarify its current rules, to help keep desperate patients away from drugs that could potentially harm them.

Source: Anna Wilde Mathews, "FDA May Broaden Access To Experimental Drugs," Wall Street Journal, November 9, 2006.