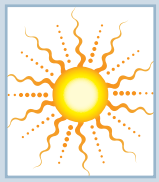
p390 Rash and risky: Should pig pancreatic cells be tested in humans?



p396 Sunny news: Evidence is mounting that vitamin D is vital for immunity.

p398 California dreaming: Robert Klein lays out the state's ambitious stem cell scheme.

Changes to US drug safety laws take center stage

The US Food and Drug Administration (FDA) moved on 9 March to toughen warning labels on a widely used class of anemia drugs, preempting a meeting in May on the issue by the agency's advisers.

The announcement came days before a US Senate hearing that focused on the agency's policing of marketed drugs, with critics escalating demands that the FDA be given greater legal authority to do so.

Since September 2004, when the widely-used painkiller Vioxx was withdrawn from the market after being linked to heart attacks and stroke, the FDA's management of drug safety has been the subject of intense scrutiny.

With Democrats in control of Congress for the first time in 12 years and a key law that funds drug review due for renewal by September, changes to the agency's toolkit for monitoring approved drugs have the best chance in years to be enacted, some experts say.

"FDA reform is front and center on the legislative agenda, the public agenda," former FDA commissioner Mark McClellan in March told an Institute of Medicine forum on drug safety.

The change is in part being enabled by new technologies that experts say would allow the agency to more actively track side effects. "It's possible to actually do these studies. And it's incumbent upon us to provide the resources and the authority and systems to make that happen," says Susan Wood, a former FDA official who resigned from the agency in 2005.

The need for tracking drug safety came to the fore at a 14 March hearing of the Senate committee in charge of rewriting the expiring law, under which drug companies pay the agency more than $300 million in user fees each year in return for speedier review of their applications.

Democratic Senator Edward Kennedy and Republican Senator Michael Enzi have written a bill that would significantly ramp up the FDA's powers to enforce the safety of marketed drugs and plan to include it in the renewed user fee law.

Some experts are wary of giving the $2-billion agency additional legal muscle without providing new funds. And others, including some patient advocacy groups, say that new mandates could have unintended consequences, such as slowing drug approvals.

Closer scrutiny: US lawmakers are proposing bills that would give the Food and Drug Administration more power to enforce drug safety.

"We can over-regulate an agency," says Ellen Sigal, chairperson of the advocacy group Friends of Cancer Research. "And I'm not sure that any of the fixes being proposed can prevent another Vioxx."

A few days before the announcement about the anemia drugs, the *Wall Street Journal* reported that the Colorado-based Breckenridge Institute had, at the request of the FDA, evaluated the agency's efforts to replace the "dysfunctional" computer system that sifts through more than 400,000 reports of adverse events each year.

The system was to have been updated beginning in 2003. But the FDA had bungled that attempt and, as a result, millions of dollars had been wasted, according to the institute. A modernized system isn't expected until at least 2009. The institute's study had been completed in November but the FDA challenged its findings and did not release the report.

Separately, the FDA on 27 February announced plans to eliminate 7 of its 13 field laboratories—which test food, drugs and medical devices for safety—and to relocate their 250 employees to the remaining six labs, prompting 20 senators to demand that the FDA commissioner "immediately suspend" the plans.

In his response, FDA commissioner Andrew von Eschenbach maintained that with overnight sample delivery, the remaining labs could take on the work and ultimately eliminate a 40% excess capacity in the current lab system.

That has not mollified critics, however. "Hundreds of specialists will be asked to move hundreds of miles away or change jobs. An unknown number of those specialists will likely leave the FDA," says Jeff Ruch, executive director of Public Employees for Environmental Responsibility, a Washington-based advocacy group.

Ruch notes that a 1996 report by the Government Accountability Office challenged a similar plan to replace ten laboratories with four 'mega-labs', in part because closing labs near ports and key food supplies could compromise public health.

In any case, after several stormy years in the public eye, the FDA can expect more scrutiny in the months to come. "Legislation is moving quickly through Congress, involving both user fees and drug safety," says Wood. "This provides an opportunity for real change at the FDA."

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