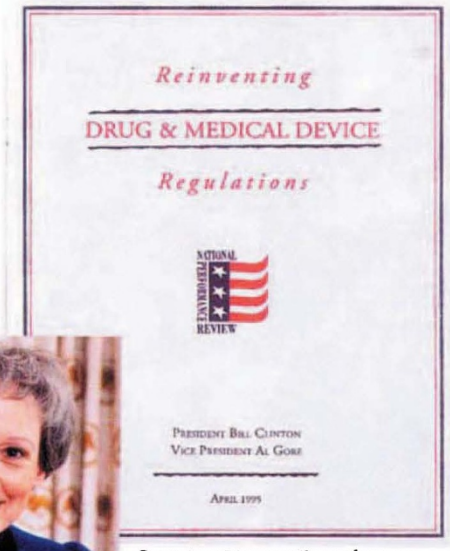
Senators voice frustration, White House proposes reform of FDA

The White House entered into the hullabaloo surrounding the way that the US Food and Drug Administration (FDA) does business when last month it released its own proposals for reform of the agency.

The 'white paper' adds the administration's voice to a debate that is attracting considerable political interest. "I believe," said Senator Tom Harkin (Democrat, Iowa), "that reform of the FDA is going to be one of the most important issues before this Congress."



Senator Nancy Kassebaum, panel chair for hearings looking at reform of the FDA.

The policy document was issued as the Senate Committee on Labor and Human Resources, chaired by Senator Nancy Kassebaum (Republican, Kansas), held oversight hearings on the FDA. Repeatedly, witnesses testifying before the senate committee and the committee's members backed the importance of the agency's consumer protection role, while, at the same time, advocating reform of the FDA.

In the broadest of terms, those reforms are philosophically similar to the White House's proposals which were released under the now unfashionable rubric of 'reinventing government'. Its aims are to reduce unnecessary regulatory burdens, first, so that FDA resources can be freed to speed product review and, second, to reduce the financial burden on industry.

In the coming months, the Republican-led Congress may well take these aims further. However, those elements of the White House's proposal that can be implemented by changes in guidelines or regulation can now go ahead without further congressional involvement.

These include the elimination of the requirement for companies producing biologics (products made from cellular material rather than by chemical synthesis) to build and have certified a full-scale plant before receiving approval for their product. Instead, the agency would review a small pilot plant, a change that could save biotechnology companies many millions of dollars. Similarly, the white paper calls for a relaxation of the regulations that govern modernization of existing manufacturing plants.

Other proposals (which will require legislation) include bringing the regulation of insulin and antibiotics in line with that of other drugs intended for humans. Currently, the regulations for insulin and antibiotics are more stringent, because when these were first introduced, the manufacturing processes were less sophisticated than they are today.

The Biotechnology Industry Organization welcomes the changes, but, says Alan Goldhammer, director of technical affairs for the trade association, "We are disappointed they did not take up some of our other suggestions, such as privatizing parts of the process or deregulating phase I trials."

Phase I trials establish drug action and levels of tolerance. Investigators must submit their proposals both to the FDA and their local Institutional Review Board (IRB). The former looks at the science and the latter, comprising scientists, physicians and lay people, looks at study design, safety and ethical issues. Industry would like to see the local review boards take responsibility for the science too.

In testimony to Kassebaum's committee, Mark Novitch, a professor of health-care sciences at the George Washington University Medical Center, said: "Congress should authorize FDA to delegate to IRBs not only ethical review, but the scientific review of early clinical research as well."

Novitch argued that involving the FDA at this early stage means that data have to be developed with a "pharmaceutical elegance" at a stage when it does not help protect human subjects. Giving local review boards more authority would give FDA more time for reviewing new drug applications, he added.

During the coming months, Kassebaum intends to hold more hearings focusing on other proposals for FDA reform. Such attention is hardly surprising given the enormous impact the FDA has on the social and economic life of people in the United States. According to official estimates, 25 cents of every dollar spent in the US buys a product regulated by the FDA. Those products include drugs, both prescription and over-the-counter medications, medical devices, food and animal drugs.

It is in this environment that the FDA must face its critics. "As a regulator," says David Kessler, the FDA's commissioner, "you sometimes have to say no and that does not make you popular." Yet current criticism seems to extend beyond the inevitable unpopularity of a regulator.

During Kassebaum's hearings, Charles Edwards, a former commissioner of the FDA and chair of an advisory committee set up by the US Department of Health and Human Services from 1990 to 1991 to study the FDA's role as a regulatory agency, criticized the paternalistic tendencies of the agency.

Other senators told Kessler that they hear on almost a daily basis from people in industry concerned about intimidation and the confrontational attitude of the agency. Kessler responded that as regulators, the agency has to insist on having those data. "Yes," said Senator Judd Gregg (Republican, New Hampshire), "you need to follow the rule, but we are hearing that there are unwritten rules . . . this is a persistent pattern, more than anecdotal."

More worrying still for the agency, Senator Barbara Mikulski (Democrat, Maryland), while sympathetic to the agency's mission, warned Kessler: "There is enormous frustration with the agency . . . that must be acknowledged . . . you really have to get with the programme".

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