NEW DRUG REVIEW

FDA Sets Out to Hire 600–And Image Is a Problem

David Kessler, commissioner of the Food and Drug Administration (FDA), calls it "the most major change" at his agency in three decades. He's talking about a bill passed in the waning hours of the 102nd Congress that will permit the FDA to hire 600 scientists to augment its current force of 1000 chemists, pharmacologists, microbiologists, and other researchers who review safety and efficacy data on novel drugs. The funds for this massive expansion will come from "user fees" Congress has now allowed the FDA to charge companies for reviewing their products (*Science*, 16 October, p. 397).

The driving force behind this sea change is a wave of complaints from drug companies and patient groups, which contend the FDA takes too long to approve new drugs. The Pharmaceutical Manufacturers Association estimates that in 1991 it took the biologics and drugs divisions an average of 21.4 and 30.3 months, respectively, to approve a new drug. With his new army of reviewers, Kessler says he intends to reduce the waiting time to 6 months in the case of drugs for life-threatening diseases such as AIDS, cancer, and Alzheimer's, and 12 months for most other drugs.

But to do that, Kessler must overcome a daunting challenge: Even in today's tight job market, some analysts think the highly trained scientists the FDA needs may shy away from the agency because the work there isn't very intriguing scientifically. Moreover, would-be drug reviewers are likely to be put off by the snowdrifts of paper that blanket the agency—because the FDA has largely failed to computerize the applications process. The agency will have "a big challenge in recruiting the number and quality of people," predicts Harvey J. Berger, chairman and chief executive officer of Cambridge, Massachusetts-based Ariad Pharmaceuticals Inc.

But Kessler is undaunted and he's made it clear he's working overtime to attract the scientists he needs. He's fighting to overcome the agency's poor image: The FDA is "a sexy place to work," he told *Science*, not "a bunch of green-eyeshade bureaucrats." Furthermore, he says, plans are in the works to plow the paperwork snowdrifts by introducing much-needed computer systems.

Kessler's number one target is medical officers: The FDA plans to hire 127 over the next 3 years. But the agency also needs scientists to do basic research: 85 chemists, 68 biologists/microbiologists, 39 pharmacologists, and 33 biostatisticians. To make recruiting easier, many of the new hires will be young scientists who've just finished postdocs, according to Mary Jo Veverka, the FDA's senior adviser for management and systems. She says the FDA intends to begin the first round of hiring next summer, at the end of the academic year, when post-docs often draw to a close.

No matter how attractive Kessler tries to make the job seem to researchers, the fact remains that, for the most part, scientists who join the FDA will have to steel themselves to spending much of their time working a desk job. And the amount of data that crosses a drug reviewer's desk is immense: Last year, at the FDA's Center for Biologics, Evaluation, and Research, which reviews new biotech drugs and processes, 332 staff scientists were responsible for reviewing 46 product applications, 504 drug therapies that companies hoped to test in clinical trials, and 6340 packets of additional information on drugs that were already in clinical trials.

But don't let the dreary data crunching fool you, FDA officials insist. "Drug evaluation and review is becoming almost a discipline unto itself," Kessler says. He bases his claim on the fact that reviewers need to combine a highly specialized science background with expertise in judging a drug's safety and efficacy. To retain their scientific skills and get a break from the paper chase, many reviewers spend a day or two a week in the laboratory and some physician-reviewers spend a comparable amount of time in private practice.

Much of that research is aimed at setting "reference standards" for industry, says Ken Seamon, associate director for research at the division of biologics. Recently this has included developing guidelines for how biotech firms should characterize cell lines that produce biologics and for manufacturing vaccines and therapeutic monoclonal antibodies. To a lesser extent, scientists at the FDA's Center for Drug Evaluation and Research, which evaluates drugs developed using traditional pharmaceutical methods, does similar research.

In addition to spreading the workload over more reviewers, the FDA will use some of the user-fee revenue to bring its review procedures out of the Xerox Age and into the Computer Age. "If we can get rid of the tedium and drudgery of going through stacks and stacks of paper, then we can make the science investigation [of reviewing an application] that much more exciting," Veverka says.

To that end, the FDA will sink about $6 million a year into information systems to streamline the review process. This isn't a new concept at FDA: The agency's drug division began accepting applications on disk in 1985. For the most part, reviewers prefer computerized submissions because they allow them to compare and annotate data sets more easily than shuffling through stacks of paper, Veverka says. But 7 years later, few companies submit their applications on disk—and those that do submit them in a variety of formats. Veverka calls this system "very inefficient" and plans to launch an effort in the spring to standardize computer submissions. The biologics division is in an even more primitive stage, where, Veverka says, "I don't know if any [product applications] are coming in on computer."

If Kessler is able to find all the new scientists he needs, he hopes that this hiring binge will do what Congress expected and help speed the drug approval process. "We know how to manage this process," Kessler says, "we just need more bodies." Now his challenge is to find them.

–Richard Stone

FDA REVIEW JOBS CREATED FROM USER-FEE REVENUE (FDA projections)

Staff	current	1993	1994	1995
Medical officers	175	236	263	302
Chemists	126	150	174	211
Pharmacologists	60	72	83	99
Microbiologists/biologists	164	184	204	232
Biostatisticians	62	77	85	95
Biopharmaceutical scientists	43	50	57	66
Other professionals	135	152	156	161
Support staff	124	146	175	202
Compliance	51	76	85	95
Field	16	41	49	58
Information management	17	24	27	32
Program management	14	21	41	50
Totals:	**987**	**1229**	**1399**	**1603**