

IOM Faults FDA for Lack of Postmarketing Focus

BY ALICIA AULT

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The Food and Drug Administration should shift its emphasis from the preapproval period to postmarketing, when new drugs pose the greatest risk of safety problems, a sweeping report from the Institute of Medicine recommends.

Numerous safety-related issues over the past few years—including the widely publicized recall of Vioxx (rofecoxib), and struggles over labeling changes for antidepressants—have led to a lack of confidence in drug development and regulation, according to the 15 experts impaneled by the IOM.

“The credibility of FDA, the industry, the academic research enterprise, and health care providers has become seriously diminished in recent years,” the committee said in its report.

The FDA, in particular, has floundered, hampered by a lack of funding and mismanagement that has led to internecine strife and miscues that may have resulted in delays in addressing safety issues, said the panel, which was made up of academicians, ethicists, and the head of the U.K. Medicines and Healthcare Products Regulatory Agency.

“FDA’s reputation has been hurt by a

perceived lack of transparency and accountability to the public, a legacy of organizational changes that have not been completed or sustained, and an apparent slowness in addressing lack of sponsor compliance,” according to the report, “The Future of Drug Safety: Promoting and Protecting the Health of the Public.”

The committee recommended that the FDA should consider requiring new molecular entities to carry a special caution that the products’ true risks and benefits are unknown.

The FDA also should consider restricting or banning direct-to-consumer advertising of those products during that early marketing period, said the committee.

After 5 years, the FDA should formally review all the available data on those products and publicize the findings, said the panel.

In addition, results of any phase II-IV clinical trials that are submitted to the FDA should be published on the Web site www.clinicaltrials.gov.

Given that most label changes are voluntary and that many companies have

not conducted the requested postmarketing studies, the FDA needs more power to enforce regulations, including the ability to more quickly and directly levy fines or secure injunctions against companies that do not comply, the committee said.

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The FDA should not be given unilateral authority, however, said the panel. “We understand that offering discretion does not mean offering dictatorial power,” said R. Alta Charo, a bioethicist at the University of Wisconsin Law School, Madison.

Among the panel’s other recommendations:

► FDA funding and staff should be vastly increased.

► FDA commissioners should be appointed to a 6-year term in order to bring

stability to the agency’s leadership.

► Staff from the FDA’s Office of Surveillance and Epidemiology should join the teams that review new drugs, to increase the safety focus from the start.

► At least 60% of the membership of each FDA advisory committee should have no significant financial involvement with the sponsors of the products being reviewed.

Some of these changes—such as a shift in resources from the preapproval to the postapproval side—could be done administratively. Others, however, such as giving the agency new enforcement authority, would require an act of Congress.

In a press briefing after the report was released, FDA officials acknowledged that there have been some difficulties, but they largely deflected the criticism by instead discussing initiatives the agency has undertaken in the last 2 years to shore up postmarketing safety efforts.

“The FDA has led an aggressive effort, which includes developing new tools for communicating information to patients and new resources for drug safety, to improve the management of the process for how we uncover and communicate important drug safety issues,” said acting FDA Commissioner Andrew von Eschenbach at the briefing.

Dr. Janet Woodcock, deputy commissioner for operations, said that the Center for Drug Evaluation and Research “has recognized a number of these issues for quite some time and has been systematically addressing them,” by doing things like establishing a drug safety board.

“We are committed to continuing to address the issues that have been raised after we’ve fully absorbed this report,” she added. ■

How to Find and Keep Top-Notch Gen-X Office Employees

BY ERIK L. GOLDMAN

Contributing Writer

SAN DIEGO — Two major converging demographic trends will amplify the importance of finding good office staffers at the same time as it will become ever more difficult to do so, Dr. Larry Anderson said at the American Academy of Dermatology’s Academy 2006 conference.

Growth of the U.S. labor force has remained nearly flat since the late 1990s. During this period the population of younger working people shrank by about 14%. That’s bad news for the 80 million Baby Boomers who will require increasing levels of medical and other services. Retirees are the fastest-growing segment of the population, but the 20-something workforce is the slowest-growing segment.

“In the next decade, we’re expecting to see a 30% shortfall in younger workers, and this will persist for about 40 years,” said Dr. Anderson, a dermatologist in private practice in Tyler, Tex.

“During this time our services will be needed more and more, and it will be harder for us to get and keep good employees.” In response, physicians need to see their employees as an asset and develop an office culture and work environment that attracts and nurtures the best and the brightest.

In terms of employer-employee relations, physicians are facing what amounts to a significant generation gap. According to a recent AAD survey, 27% of all AAD members are 41-50 years old, and 29% are 51-60 years old. “More than 50% of all dermatologists are Boomers, with a mean age in their early 50s. Our employees, howev-

er, are in their 20s and 30s,” he said. While attitudinal differences between the Boomers, born between 1943 and 1964, and the so-called Generation X, born from the mid-1960s to the mid-1980s, may not be as great as the cultural divide between the Boomers and their Depression- and World War II-era parents, it can be much greater than many people realize, especially when it comes to matters of career and identity.

In terms of work styles, the Gen-Xers tend to be highly independent. “Remember, these are the latchkey kids all grown up.” In their professional lives, they want to know what has to be done, why it must be done, and when they must deliver. Beyond that, they want to be left alone.

This generation has the “question authority” attitude in spades. “With this generation, rules don’t count unless they have input and understand the rationale,” Dr. Anderson said. In managing Gen-Xers, it is best to give them guidelines, while at the same time letting them into the planning process and allowing them to figure out the implementation.

Remember that Gen-Xers grew up in a time of unprecedented job mobility and career flexibility. They don’t expect to work at any one company or office for their entire adult lives.

Gen-Xers are nearly allergic to office politics, and they resent favoritism and nepotism. They react badly to micromanagement, and they dislike it when their ideas, opinions, and suggestions are categorically ignored.

Dr. Anderson has found that team-based

management works very well with Gen-X staffers, rather than top-down command and control strategies. “They view things according to the notion that a good idea is what gives power, not simply position.”

Positive feedback, constructive criticism, meaningful raises, and frequent “thank yous” go a long way with Gen-Xers. They also appreciate learning new skills and job situations that offer diverse and challenging experiences, rather than simple routines. “They like to experiment, and they want fresh experiences.”

In terms of financial issues, be aware that Gen-Xers are often struggling. At the same time, they tend to be less motivated by money than many Boomers are, and they strongly resist being bought off. Given that most medical office jobs in a given geographic area will pay more or less the same salaries, money is usually not an issue as long as you’re paying market rates.

“You won’t necessarily get a better employee by offering a few dollars more,” Dr. Anderson said. But you will if you show that you can offer a flexible, team-based work situation; a lively office atmosphere; and a culture that respects their intelligence, input, and extraoffice interests.

The single most important factor in creating a happy staff is in selecting people whose personalities and characters fit well together. Remember that technical skills can be learned and developed along the way. A candidate who is a natural fit with your office culture will, in the long run, be a much better bet than a highly skilled but difficult person who does not mesh well with the rest of the staff. ■

Tips for Managing Gen-X Staffers

- Listen with full attention, speak respectfully, and praise good work often.
- Create an atmosphere in which it is okay to respectfully disagree, and remember that your Gen-X staffers will be far more responsive if you explain why you do things your way.
- Keep in mind that many Gen-Xers don’t have long attention spans, so make your communications and instructions concise and to the point.
- Gen-Xers are computer savvy, so put your communications, guidelines, and requests online or in electronic form.

- Gen-Xers are learning oriented, so conduct periodic learning inventories and ask them what they’re learning during the day-to-day operations of your office.
- Encourage your staffers to cultivate their lives outside the office.
- Encourage teamwork and help foster a familial atmosphere in your office.
- Whatever it is that you preach, make sure you’re practicing it.
- Lighten up and learn to be flexible.

Source: Dr. Anderson