

# Goddard: Revolution Comes Hard

by Barbara J. Culliton

Commissioner James L. Goddard came to the Food and Drug Administration a year ago like a missionary to a pagan land, prophesying the coming of new blood, new talent, and new protection for the American consumer. Goddard hasn't lowered his sights, but there are signs the revolution may take more time than he planned to allot—and perhaps more sweat as well.

For years FDA had been plodding along with a staff of scientists who were not geared to the fast moving pace of scientific developments and a commissioner geared to the decades-old problem of quack medicine, but who did little to make the agency grow up to its responsibilities.

**Goddard found** a tremendous backlog of drug applications to clear out, a longer backlog of pressing decisions waiting to be made and a desperate need for better studies on drug efficacy as demanded by the Kefauver-Harris Drug Amendments of 1962. Good people were hard to attract; the reputation of FDA was not much of a lure.

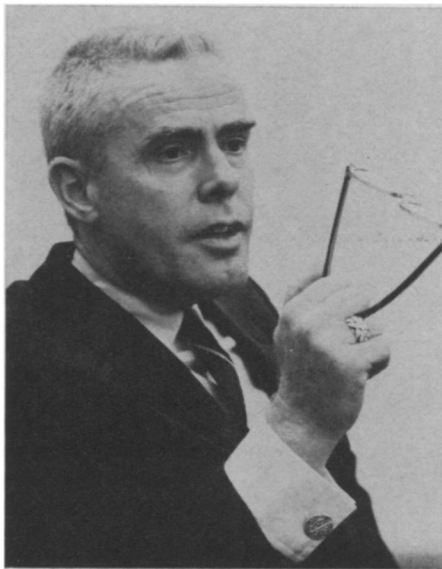
Reform, at first, came fast and furiously as one by one the errors of the past were uncovered, confessed where necessary, and righted. Clinical testing of DMSO, the widely publicized, highly dangerous "wonder drug" that was being blatantly misused by eager researchers, was curtailed; antibiotic throat lozenges were pulled off the market because they were ineffective; a major drug company got a public spanking for advertising a contraceptive pill before it was approved and the biggest and most respected firms in the pharmaceutical industry were taken to task for sloppy practices.

**FDA should be run,** Goddard declared, according to the letter of the law, and that law is written in the 1962 amendments; drugs must be not only safe, but must do what they are supposed to do—no more, and certainly no less. And not only new drugs, but old and established drugs as well.

In lieu of his predecessors casual and trusting relationship with the drug industry, Dr. Goddard has rewritten the rule book. "I'm the boss," he says in just so many words—not entirely to industry's pleasure.

Some drug makers think the letter of his law stands in the way of sound medical research, and clinical testers fear enforced demands that they obtain written and informed consent from any patient before administering an experimental drug.

Goddard denies charges that being pro-consumer means being anti-industry. He wants cooperation between FDA and industry and insists it is more than just a platitude that both sides share a common goal in preserving and improving the health of the nation.



FDA's Goddard: "I'm the boss."

He makes it perfectly clear though, that from where he sits, cooperation depends on the drug industry meeting its responsibilities and behaving reasonably. In a round of speeches in the first few months of his tenure the new commissioner called the drug companies irresponsible in no uncertain terms.

**The congenial** but driving head of FDA is an admittedly ambitious man who enjoys FDA's new found fame and his place on the front page.

Before assuming command at FDA, Dr. Goddard, who holds the rank of rear admiral in the Public Health Service, was chief of PHS's Communicable Disease Center in Atlanta, Ga. Looking ahead, some people speculate the cool, confident officer-doctor-administrator may be the new Secretary of Health when the proposed reorganization of the parent Department of Health, Education and Welfare comes about.

"He certainly has the paper qualifications for the job. It's ultimately a matter of personality," says one Washington observer.

"He's much too abrasive to rise much higher than he has," according to another. "Like all revolutionaries, he's going to make one mistake too many, and that will be the end."

As do most ambitious potential candidates, Dr. Goddard assures question-

ers he plans to stay at FDA "at least five years." The first is up this month.

**Though progress** in some areas, particularly high quality personnel, may have been slow, many of the dusty files at FDA have been cleaned out. But the enthusiasm and the promises of last year's early speeches have not all been met, giving his supporters reason for disappointment. He hasn't managed to do in a year all the things he promised but four are left to make good his word. People close to FDA are anxiously watching and waiting. Most of the revolutionizing, they say, has been shooting fish in a barrel; cleaning up the backlog was easy. From here on in he will have to find his own targets. And he's already finding that the food and drug industries, with powerful friends in Congress, are an elusive target at best.

**But he is zeroing in.** With implementation of the drug laws in process, Goddard is widening FDA's horizons. Drug efficacy, food safety (particularly the salmonella problem), food frauds, food additives and daily vitamins have all come under his eagle eye, and his watchfulness is not likely to let up.

What FDA needs in the long run, and what Goddard is trying to find, is, quite simply, smarter people. In order to keep up with industry, FDA needs better scientific expertise and to this end, the commissioner is working on a program of continuing education to allow scientific personnel to take occasional leaves to spend a year in the academic world, and has plans to install a computer system that will eventually make reams of information instantly available to every scientist.

**In the meantime,** while these long-range plans are taking shape, Dr. Goddard has come up with another solution to the manpower shortage—the draft. This year 65 medical doctors from the Public Health Service, many of whom are meeting military obligations, will be assigned to help FDA clear out its backlog of applications. With the help of this vitally needed scientific competence, the new blood and new talent everyone has been calling for, FDA's energetic chief expects years of bureaucratic backlog to be cleared out by July 1.

"Go-Go Goddard" is what they call him back at the office, and he doesn't seem to mind. It's just that he may be go-going with a little less speed and more deliberation than he and everyone else expected.