

FDA Scientist Survey Summary

In late 2002, the Department of Health & Human Services Office of Inspector General asked FDA scientists a battery of 52 questions yielding the following results:

I. Safety of Drugs on the Market

- Two-thirds (66%) of respondents lacked confidence the agency “adequately monitors the safety of prescription drugs once they are on the market;”
- Only 12% of scientists were completely confident that FDA “labeling decisions adequately address key safety concerns” while 30% were not at all or only somewhat confident; and
- Only 13% of scientists were completely confident that FDA “final decisions adequately assess the safety of a drug” while nearly a third (31%) were only somewhat confident and 5% lacked any confidence in those decisions.

II. Scientific Quality in FDA

- With drugs classified as a priority (allocated only a 6-month review period), well more than half (58%) of scientists did not believe FDA has enough time “to conduct an in-depth, science-based review” of a new drug; and
- Nearly half (48%) reported that FDA does not do enough “to monitor and improve” its drug assessment process.

III. Scientific Dissent Within FDA

- Nearly one in five scientists (18%) said that they “have been pressured to approve or recommend approval” for a drug “despite reservations about the safety, efficacy or quality of the drug;”
- Less than one third of scientists (29%) felt that the “work environment” at FDA allowed wide leeway for “expressions of differing scientific opinions related to” new drug application decisions, while 21% said the work environment offered little or no room for dissent, with fully half (50%) answering that scientific dissent was allowed only “to some extent”; and
- Less than one in five (17%) felt the agency had “adequate procedures in place to address scientific disagreements” to a “great extent,” while 45% felt adequate procedures existed only to “some extent” and more than a third (38%) said procedures for resolving dissent existed only to a “small extent” or “not at all.”

The HHS/OIG surveyed 846 FDA scientists with a 47% rate of return.