The work of FDA's Litigation and Recall Staff primarily involves matters leading to contested litigation involving drugs. These matters include administrative hearings, civil and criminal suits in the federal courts, and grand jury investigations. The work entails carefully studying evidence that forms the basis for the government's case, developing investigations to beef up the government's evidence when necessary, studying the evidence of the opposing party, designing investigations to explore its weaknesses, identifying expert witnesses, supplying them with appropriate material to review, studying the scholarly literature to find texts and reports to support the government's position and/or to provide material for cross examining opposing experts, supervising the preparation of the file of evidence, indexing and cross indexing it so that it can be found, interviewing key witnesses, developing testimony, assisting FDA's attorneys in the process of discovery, and at trials and hearings where contested issues are resolved.

This staff's efforts have made indispensable contributions to successful development and prosecution of cases of major public health importance. These include the Selacryn case which represented the first successful effort to enforce adverse reaction reporting provisions of the statute, the IBT fraud prosecution, and the prosecution of Norwich which resulted in a broad, unprecedented judicial interpretation of the definition of sterility. We also developed the agency's single, major, current criminal enforcement initiative in the field of health fraud.

We have given credibility to implementation of the effectiveness provisions of the Kefauver-Harris Amendments of 1962 by developing cases to sustain the Center's position in administrative hearings involving oral proteolytic enzymes, Thorazine and the use of major tranquilizers in the treatment of non-psychotic anxiety, Combid and Darbid and the use of such combinations for GI disorders, and, in the Marax hearing, the use of triple combination products in the management of asthma. Significantly, in these cases, our work has often provided a basis for negotiated settlements in which contested issues were resolved in the public interest on scientific rather than adversarial grounds. Investigations we initiated have turned up misconduct and fraud on the part of clinical investigators who had previously been investigated but not proven responsible for such conduct.
Our work has been significant in the development of important segments of the regulations. These include the laboratory controls segments of the current good manufacturing practice regulations, the provisions of the good manufacturing practice regulations which control drug salvaging, and the good laboratory practice regulations. We have also provided support for the department's efforts to defend the "MAC" regs and for agency policy concerning "paper" NDA's.

As presently constituted, the litigation function of the staff is carried out by 7 professionals, two technicians, one clerk, and a secretary. The professionals work chiefly with lawyers in the Office of General Counsel. The staff also has a director who assigns work but who is not ordinarily otherwise involved in the working relationship between staff and trial attorneys.

The staff's central priority is meeting the real time demands of litigation. Dissolving the staff and distributing its personnel among divisions in the Office of Compliance of the Center for Drugs and Biologics will place this priority into competition with the other priorities of the divisions. Competing demands arising from the divisions' responsibilities but not part of our staff's responsibilities could easily weaken the agency's ability to deal with the demands of litigation. It should not because active litigation is supposed to be a priority throughout the agency but it has been this staff's reason for existence. Meeting deadlines and doing it excellently well will be transformed from a source of pride and achievement into an onerous burden requiring that other legitimate interests, factors upon which performance is determined, be set aside. More likely than not, this will weaken FDA's capacity to meet the demands of litigation.

The outcome of litigation has a kind of finality that is not found in most other kinds of business conducted by the Food and Drug Administration. Failure ordinarily has irreversibly adverse consequences. FDA's litigation usually involves important public health interests. Any weakening of FDA's abilities to meet its demands can be expected to have serious and irreversible adverse public health consequences. No such action should be taken unless there are countervailing public health benefits. No such benefits have been identified by the architects of the staff's demise.

Having a small staff that specializes in regulatory management affords important benefits to the agency that would be lost if the staff is dissolved. It gives FDA the flexibility that is essential to meeting the demands of litigation. When a suit is filed against the agency or a judge suddenly orders a hearing or a state prosecutor suddenly finds the need for help, this staff gives FDA the depth and reserve that makes it possible to respond effectively. That reserve will be lost if the staff is destroyed. It will also limit FDA's ability to meet emergency needs in FDA's own litigation. As matters now stand, in an emergency, any professional member of our staff can pick up, fill in for, or help other members on any kind of litigation. Dividing the functions up can only reduce FDA's effectiveness.
Much of the great personal labor that goes into developing important cases will be wasted. The waste is twofold since someone must pick up the strands. For many years, our staff has provided the continuity that gives stability to complex litigation. The breakup will destroy that continuity. It is terribly ill conceived. Breaking up the staff and reassigning responsibilities will necessarily involve changing horses in midstream. There will be multiple changes. These changes can only harm cases in progress for months or years. In every instance, the potential is that the harm will be irreversible.

Having a staff that specializes in litigation provides an environment in which the skills and materials needed to meet the needs of litigation can be passed on to others. Destroying the staff will deprive the agency of a resource that it cannot afford to lose or be without in years to come. The predictable consequence of this will be regulatory failures in matters of major public health importance.

Managing litigation requires a small physical plant. In the modern world, there must be word processing equipment, copying equipment, files, material processing and storage space, and a small, integrated, skilled, and well trained support staff. These resources need to be organized and situated so that they can interface efficiently and effectively with FDA’s attorneys, the medical library and divisions, the law judge, and the dockets management and file facility. Last year, these needs led the agency’s senior management to overrule an effort to remove the staff from the Parklawn Building. The need to preserve the facilities and resources that make it possible for this small staff to operate here is more acute today that it was a year ago. This is because uprooting the staff and dismembering it will probably be an irreversible impediment to its restoration and continued effective function. Moreover, duplicating the qualified support staff in each of the several divisions would be impossible initially and wasteful in the long term. Replicating the physical facilities would also be wasteful.

Only two reasons have been advanced to justify dissolving the Litigation and Recall Staff. One is that other divisions need this staff’s expertise. The other is that grade level of supervisors in the divisions must be protected by increasing the number of people they supervise.

The claim that existing divisions need the expertise of this staff is not well founded. The divisions may need expertise in work that is not ordinarily the responsibility of the staff but not in the work that is our principal specialty - except to the extent that the regulatory management function itself is divided and redistributed. The exception cannot prove the rule unless there is adequate independent justification for the action.

The situation is analogous to what would happen in a medical school if the dean called together the department of surgery and dissolved it, distributing its members to the various medical departments. This would not be in the best interests of the surgical service, patients who needed surgery, or of patients who came to the medical departments in need of medical evaluation and therapy. This is an irrational way to deal with a specialty that consumes few resources and that serves critically important agency functions.
Separating such regulatory functions as managing hearings on the one hand and handling seizure cases on the other will introduce waste and inefficiency into the process of regulatory management. Although hearings are very lengthy and burdensome, it is often possible to fit in other smaller, important, regulatory projects so that we can keep several small, worthwhile cases underway at the same time in addition to long-term regulatory projects. If the functions are divided, this capacity will be lost or, at least, materially reduced. People assigned to litigation in the unit that handles hearings will not be available in other units to work on injunctions, prosecutions, or similar matters.

It is not difficult to argue that, as an institution, the Office of Compliance is suffering from hypertrophy of the bureaucracy. It was not too long ago that a single division had most of the responsibilities of what is now three divisions and numerous branches an office with 5 divisions. One driving force behind diversification was that it became very difficult to reward superior performance by promoting, on the basis of their expertise, staffers who did outstanding work. Using promotions for this purpose became difficult because of the government's effort to fight "grade creep." It can be difficult to distinguish between grade creep and promotion used to reward truly outstanding performance.

The bureaucracy is not stupid. Its response to constraints on grade creep was creeping diversification. Outstanding employees would be made branch chiefs and three less experienced replacements would be brought in under them. This had two unfortunate consequences. It put the work into the hands of less experienced people and it separated the really skilled people from the work itself. This is a perfect example of the operation of Parkinson's Law.

The Litigation and Recall Staff is being destroyed in a stop-gap effort to preserve a bureaucracy and grade structure that is unnecessarily complex and costly. This reorganization will only add 6 professional, non-supervisory personnel to 3 divisions. That amounts to a fraction of a person per branch-level unit in the Office as a whole. It is questionable whether such slight augmentation will materially contribute to the maintenance of the branches. It is rumored that the Office may soon be required to give up as many as 10 professional staffers to medical review divisions in the Center. If this is true, our redistribution will not even make up for the loss.

In the Office of Compliance, one supervisor ought to be able to supervise the work of 10 to 12 professionals or para-professionals. Recent changes in administrative policy have raised the generally acceptable ratio of employees to supervisors from an absurdly low ratio of about 3:1 to about 6:1. It could and should be further increased. Our unit is being destroyed so that branches and the divisions they depend on for existence can meet the new current ratio. What will be the result if the acceptable ratio is raised to 8 or 10 or 12:1? Our unit will have been wasted and the over-differentiated branches and divisions of the Office will collapse anyway.
Destroying this staff clearly frustrates the intent of the policy of increasing the ratio of employees to supervisors. The policy cannot have been intended to destroy small, highly skilled, effective, productive units of specialists such as ours to preserve grades and overly complex structures elsewhere. In fact, the intent of the policy must have been just the opposite. Sacrificing an outstanding, small, well-integrated unit whose special skills clearly serve the interests of the Center, the agency, and the public health to avoid reform of an excessively differentiated bureaucracy is the most striking example that I have ever seen of putting the chart before the horse.

It would benefit the Center and the agency to force the Office to deal with its over-differentiation problem more directly. In addition to preserving our staff and the services we render to FDA, the Office would necessarily become leaner and meaner. This would free up people with training and experience pertinent to NDA processing, evaluation, and review who could be moved into this high priority work.

FDA's litigation workload comes from three sources. In the last few years, the lion's share of the work has come from NDA withdrawal proceedings generated by the Office of Drug Research and Review and the DESI review. Other sources of work include cases developed in compliance operations and suits against the agency. There is no necessary reason for placing the litigation support function in the Office of Compliance. It would be at least as logical for the staff to be administratively connected to the office that generates most of its work and more logical for this small unit to be on the staff of the Center's director. The needs of the Office of Compliance do not offer any kind of compelling rationale for destroying this staff or moving it out of the Parklawn Building.

FDA should also consider the message abolishing the Litigation and Recall Staff will send to the regulated industry. It is acknowledged that our record for innovation, diligence, and success is formidable. Knowledgable adversaries will respond with glee to news of the staff's demise. They will do so for good cause. FDA's regulatory capacity will be weakened. Its flexibility will be reduced. Its ability to meet the needs of the future will be impaired. The decision makes a mockery of the central commitment of Commissioner Young's action plan - to lay a foundation now for a stronger agency, an agency that will meet the needs of America in the 21st Century.

It might be argued that the destruction of the staff per se really changes nothing. All the people are still there. All the skills are still there. They are merely being redistributed. In response to this, I would point out that when you have a glass of fine wine and you break it, both the glass and the wine are still there. All that's changed is the structure, but it does make a difference.
From a personal perspective, none of the assignments created by the breakup offers any substantial appeal. I have spent almost 20 years working on every kind of contested litigation that I could get exposed to. I have worked on cases that involved new drugs, drug quality, purity, strength, sterility, good manufacturing practice, the truthfulness of claims, the adequacy of labeling, clinical studies, quackery, and fraud. Compartmentalization of the regulatory management function means that with any new assignment, the overwhelming majority of my training, knowledge, experience, and skills will go down the drain.

It is unlikely that the Division of Drug Quality Compliance, to which I will be assigned, can generate enough contested litigation to make use of my principal skills. I believe that it is fair to say that for many, many years, these skills have contributed in significant ways to every case that I have been assigned to.

My first new assignment involves no litigation at all. It will likely be to dust off the guidelines for good manufacturing practice in the production of large volume parenteral products. In the early to mid '70's, following wave after wave of recalls that shook the LVP industry, and with reports of infections and deaths attributed to sterility failures in these products, there seemed to be an acute need for regulations or guidelines to restore confidence in the nation's supply of these products. Time has passed this project by. Efforts we made to develop regulations led to a general upgrading of conditions in the industry and validation of manufacturing and quality controls. Dusting off those old guidelines seems to be a chore of almost zero priority and importance. It does not meet the measure of my skills or match them.

I doubt that this work, or any work in the division, will sustain my grade because it depends chiefly on regulatory management skills. This is the main area in which I have something of consequence to contribute to FDA. If I am denied the opportunity to work in this area, I will find less satisfaction in my work and, probably, be demoted but the agency will also lose the benefits of my special experience and talent in handling contested litigation.

Neither the branch to which I am assigned nor the one that Don Kilburn is slated to be assigned to are branches that need bodies for their continued existence. My new branch has about 11 people; Don's has 8 or 9. Our assignments seem to be complete mismatches that are not justified for either of the reasons that have been given as the basis for this action.

The plan to abolish our staff is not justified by management considerations. It is not justified from the standpoint of operations. It is not justified by any sensible regulatory strategy. It is a destructive action directed against a small unit that has served the interests of FDA and the Center faithfully, skillfully, and well. We are proud of our record. We are proud of our work. We are proud of our people. That this fine record should lead to the unit's destruction for reasons not justified by public health considerations, the dictates of good management, the requirements of effective operations, or by sound regulatory strategy is simply incredible.