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THE SUM OF ITS PARTS

Mitosis, or cell division to form two daughter cells, constitutes one of the most basic and elementary of life processes. From time to time a comparable phenomenon is encountered in other aspects of life and society, including that peculiar organizational structure called "government" that man has established for the purpose of providing an orderly system for the operation of society.

A primary feature of legislation recently introduced in the U.S. Senate under the co-sponsorship of Senators Kennedy and Javits would have the net effect of mitosis on what is now the federal Food and Drug Administration. The pertinent bills would create a Drug and Devices Administration and a Food and Cosmetic Administration. Each would be staffed, budgeted, operated, and administered completely independently of the other, in contrast to the present arrangement whereby all of these functions and responsibility fall within the purview of the FDA under the sole direction of the Commissioner of Food and Drugs.

Much can be said in favor of such a split:

(*a*) Smaller specialized agencies are more responsive and can be mobilized faster and more effectively;
(*b*) Narrowed responsibilities would enable greater concentration of attention and enhance the focusing of available resources;
(*c*) Foods and drugs are quite different commodities, having entirely different purposes and presenting basically different problems;
(*d*) The technical and scientific programs for surveillance of foods and of drugs have very little in common so that testing facilities and personnel have limited interchangeability; and
(*e*) Separate allocation of budget, manpower, and other resources would clarify the commitment actually made to each area, thereby facilitating administrative review and congressional oversight in terms of expended costs *versus* achieved results.

But by the same token, much also can be said in favor of a single unified agency:

(*a*) A single large agency has more visibility and political clout than several fragmented smaller ones;
(*b*) Internal communications are more simple, direct, and prompt within a single agency than between dual agencies;
(*c*) Despite their obvious differences, foods and drugs do have definite areas of overlap, calling for a unified, comprehensive approach—for example, drugs in animal feeds and vitamin products of various potencies;
(*d*) In the event of major emergencies, such as the botulism incident, even specialized inspectors can contribute valuable, alternate duty in a relatively unfamiliar area of activity; and
(*e*) Destructive interagency rivalries and competition for limited funds are eliminated while flexibility of resource allocation is at least possible, even though applicable opportunities may be relatively limited.

Hence, the proposal that FDA undergo karyokinesis is a complex matter requiring considerable analysis before a judgment can be rendered to the effect that it would be either beneficial or detrimental. Basically, the determination must come down to an assessment of whether in this case the whole is greater than, or less than, the sum of its component parts.

In announcing their joint bill, Senators Kennedy and Javits stated that they would be soliciting advice, recommendations, and opinions from a wide variety of sources before proceeding further with their proposal. They are to be commended for this attitude because it is evident that not only is the preferred route not yet clear but also that the decision eventually made will have a major impact on the public health and welfare. We add our sincere hope that the ultimate outcome will prove both successful and beneficial to all concerned.

—EGF