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## HAS JUSTICE BEEN SERVED?

As this column is being written, the "blue ribbon" investigative body known as the HEW Review Panel on New Drug Regulation is in the last stages of winding down its two-year plus period of existence. At least, it appears to be approaching its final demise. The group has had a long history of twelfth-hour reprieves and extensions, each coming when the Panel's life previously seemed to be terminating.

From its inception, this Review Panel has been one of the most puzzling and curious activities to hit the Washington scene in a long time.

Its formation was originally announced by former HEW Secretary Caspar W. Weinberger on March 28, 1975, principally for the purpose of reviewing the allegations by a group of disgruntled Food and Drug Administration employees of FDA misconduct in the area of approval of New Drug Applications. These dissidents had publicly charged that NDA review procedures were improperly administered by agency officials sympathetic to the drug industry, and that any efforts by FDA staff members to be objective were met with abuse, retaliation, and harassment.

If such charges had been made by only a couple of employees, they might have been dismissed as nothing more than commonplace employee disenchantment and exaggeration. However, at least a score of medical scientists openly voiced such grievances. Hence, a full investigation was in order.

But immediately, even at its inception, the Panel got off to a peculiar start. Rather than confining its purpose to a review of the allegations of the dissident employees, the Panel embarked upon a broad scale review of the entire FDA operation, the entire concept of the drug approval process, the complete philosophy of FDA objectives and management, and more. The charge given the Panel was sufficiently broad that the Panel—rightly or wrongly—chose to interpret it as so sweeping as to encompass every aspect of FDA activity, involvement, and responsibility.

Subsequently, the Panel has had a turbulent and rocky history—within its own operation, in its relation with the HEW hierarchy, and in its purposeful adversary stance *versus* the FDA.

Its original Chairman drastically dissented from the views of the Panel majority and then resigned. The initial Executive Secretary resigned because of discord with the Panel, and several successors followed in as many months. Testimony presented during Panel hearings ranged from the bizarre to the incredulous and included a "true confessions" inside view of daily conduct in the FDA's Bureau of Drugs. Staff written reports were prepared in secret, circulated confidentially, discussed in open session, and then rejected by the Panel. The FDA Commissioner was obliged to prepare a defense in the form of a report running thirteen chapters and several hundred pages and which, in turn, was subjected by the Panel to a page-by-page, point-by-point dissection and rejection. A 765-page report prepared by the Panel's special legal counsel included a recommendation for both criminal and disciplinary actions against several former and present FDA officials.

But despite its sordid operation, the Panel has worked and produced. Full meetings have been held on a regular monthly basis, lengthy interim reports have been issued on each of the many subjects reviewed by the Panel, related documents such as announcements and meeting minutes have flowed promptly and consistently from the staff office, and a series of meaningful recommendations has ultimately emanated from the Panel's deliberations.

But now that the whole operation is about to conclude, we asked ourselves: Was it all worthwhile? What was accomplished? Were the complaints of the employees which triggered the entire operation adequately dealt with and satisfactorily resolved?

In all candor, we find it hard to say. And, judging by the ambivalence of virtually all other press reports we have read relating to the Panel, it appears that other observers of the Washington scene are experiencing similar difficulty in making judgments.

In many respects, this Review Panel operation reminds us of the various President Kennedy assassination inquiries which have been similarly intense, controversial, and, yet, unfulfilling in that few real answers have been provided. In fact, whatever satisfaction has been realized is probably the result of the catharsis effect derived from engaging in this lengthy and abrasive inquiry. Only time and history will ultimately determine if the result was worth the effort.

—EGF