

The Park Case

By RICHARD A. MERRILL

Mr. Merrill is Chief Counsel of the Food and Drug Administration.

DISCUSSION OF THE *PARK* CASE¹ is an open invitation to hyperbole from both the critics and the defenders of Mr. Chief Justice Burger's decision. Representatives of the Food and Drug Administration (FDA) might be expected to call forth Justice Frankfurter's vivid statements of the high purposes of the Food and Drug Act. Advocates of acquittal, much in the nature of a second appeal to the jury, will invoke the "fundamental principles of Anglo-American jurisprudence" and the spirit of the founding fathers.

This discussion will be more useful, however, if its tone is more skeptical.

Let me begin in this vein by wondering, only half facetiously, why the *Park* decision has been made the focus of a panel on the FDA's enforcement policies. Not that the role of criminal prosecution in the enforcement of laws intended to protect consumers is not an important subject. But one may justifiably question how much the *Park* decision has to contribute to the topic.

People talk about the *Park* decision, in either hushed or angered tones, as if it had come as a surprise. Yet, since 1906, federal law has imposed strict liability on producers of food and drugs. That policy was consciously reasserted by Congress in 1938. And in the famous *Dotterweich* case in 1943,² the Supreme Court confirmed that Congress' judgment was both sensible and constitutional. Indeed, Chief Justice Burger himself spends a good portion of his opinion in *Park* explaining that criminal liability without proof of "awareness of some wrongdoing" is by no means novel.

¹ *U. S. v. Park*, 95 S. Ct. 1903 (1975).

² *U. S. v. Dotterweich*, 320 U. S. 377 (1943).

Facts of the Case

Justice Burger's opinion, to be sure, contains some fine round words, but they do not account for the stir the *Park* decision has caused. Nor, I submit, do the facts of the case.

Very few people have seriously suggested that Mr. Park was unjustly convicted of a misdemeanor. Consider what the government was able to prove at the trial:

(1) FDA inspectors had, on three separate occasions, discovered serious sanitation violations in warehouses operated by Acme Supermarkets. It has never been suggested that no violations of law occurred.

(2) The last two inspections conducted by the FDA were of the same Baltimore warehouse . . . demonstrating either a persistent problem, or a persistent indifference to its solution.

(3) Mr. Park acknowledged that not only was warehouse sanitation one of the matters for which he accepted responsibility, but that he had specifically delegated to subordinates the job of solving the problem in Baltimore.

(4) Mr. Park was aware that the problem, discovered first in Philadelphia and subsequently in Baltimore, was not being solved or, at least, was continuing. He was, in short, on notice that his "system" was not working.

In the face of this evidence, under the standard announced in *Dotterweich*, it cannot be a surprise that the jury convicted or that the Supreme Court affirmed.

Strict Criminal Liability

I do not want to be understood as denigrating the efforts of the Supreme Court on our behalf. The *Park* opinion is a workmanlike product, and it reconfirms both the importance and the legitimacy of strict criminal liability for violations of the Federal Food, Drug and Cosmetic Act. But it is also an unsatisfactory decision in some ways, for it leaves troubling questions unanswered.

Two that come quickly to mind are: (1) the Court's failure to explain precisely what the government must show to establish that a defendant had a "reasonable relation" to the violations charged; and (2) the Court's cursory treatment of what is becoming known as the "impossibility" defense.

Two cases now before the Ninth Circuit Court of Appeals, *Starr* and *Hala*, will soon speak to the latter issue. Therefore, I shall not explore it further.

On the former issue, which is really the heart of the matter, the Court says essentially that the facts proved by the government in *Park* clearly demonstrated such a relationship and that the jury instructions, though perhaps lacking in specificity, were adequate to focus the jury's attention on the facts before it.

It may not, however, be possible to do much better with this issue. We struggle very hard in reviewing proposed prosecutions to satisfy ourselves that the evidence of individual involvement—of opportunity to know and ability to prevent or correct—is adequate enough to justify prosecution. We are attempting to articulate and publish criteria for recommending prosecution, because we recognize that the uncertain scope of the *Park* decision—indeed, of the Act itself—imposes on us an obligation to deploy this ultimate sanction with great care.

Basic Ground Rules

The government's brief in the *Park* case identifies certain basic ground rules. First, we almost always will include one or more individuals as defendants: corporations alone do not commit crimes. At the same time, we will not include individuals who lack authority to prevent or correct violations or who could not be expected to have been aware of violations in the reasonable exercise of their corporate duties. And, even if investigation discloses the elements of liability, ordinarily we do not recommend prosecution unless the defendant, after learning of the violations, fails to correct them or to make changes to prevent their recurrence.

Our standards for reference of cases to the Department of Justice focus on continuing violations, on violations of an obvious and flagrant nature and on intentionally false or fraudulent violations.

These criteria may sound too flexible but, in practice, they produce a high degree of continuity and consistency in our recommendations. Moreover, it is important to recognize that the prosecutory function inevitably entails the exercise of judgment. The scope of our discretion under *Park* is not, I submit, notably different than that exercised by most local prosecutors.

This leaves the central issue of whether strict, though not absolute, criminal liability is an appropriate feature of a scheme for regu-

lating foods, pharmaceuticals, and medical equipment. In my view, the answer is self-evident. The other sanctions provided by the Act—or *providable by Congress*—would not by themselves assure the degree of punctilious concern for product integrity and safety to which consumers are entitled and too often fail to receive.

Testimony Before Congress

The point has since been more eloquently, but never more forcefully, stated than by Charles Wesley Dunn, who testified before Congress in 1948 *on behalf of* the Grocery Manufacturers of America, the American Pharmaceutical Manufacturers Association and the New York State Bar Association. The occasion was a hearing to consider a bill to amend the criminal liability provisions of the Act, a bill inspired by reaction to the *Dotterweich* decision. On that occasion, Mr. Dunn declared: "It has always been the situation under the Food and Drug Law . . . that intent is not an essential ingredient of the offense. If you make it so, you simply nullify, in effect, the practical value of these laws."

Congress wisely listened to Mr. Dunn then. The jury is still out on whether Congress will exhibit the same wisdom this time around.

The proposed Consumer Food Act, recently reported by the Senate Commerce Committee, includes a provision that would require the FDA to prove that a defendant charged with violating the food provisions of the Act did so knowingly, willfully or negligently. And it is widely rumored that the House Committee on Interstate and Foreign Commerce will be invited, and possibly persuaded, to amend the device bill so as to limit criminal liability to cases in which the FDA could prove that the defendant acted knowingly or willfully.

The latter of these proposals would, in Mr. Dunn's words, "simply nullify . . . the practical value" of the Federal Food, Drug and Cosmetic Act. The former, though less destructive of the Act's basic purposes, represents a fundamental shift in Congressional philosophy respecting consumer safety. And only Congress could then answer for the practical effect of its adoption on the willingness of individuals engaged in the production of food, drugs, devices and cosmetics to make the commitment necessary to guarantee that their products are safe.

[The End]