



Criminal Liability Under the Food, Drug, and Cosmetic Act

Citation

Criminal Liability Under the Food, Drug, and Cosmetic Act (1995 Third Year Paper)

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Criminal Liability Under the Food, Drug, and Cosmetic Act

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Author: 104-2081-40-57

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The criminal provisions of the Federal Food, Drug, and Cosmetic Act (FDCA) and the judicial interpretation thereof afford the Food and Drug Administration (FDA) great discretion, in determining both when and against whom criminal prosecution is warranted. Though it may employ a wide variety of enforcement mechanisms, the FDA has relied in recent years ever more heavily on criminal proceedings.² Absent appropriate guidelines, however, extensive use of criminal sanctions to enforce the FDCA potentially leads to costly, inefficient, and unnecessary prosecutions. This paper attempts to define such guidelines in the context of criminal liability for corporate officers and employees.³ First, the paper will describe corporate liability under the FDCA. Next, it will utilize economic tools to propose guidelines to help determine when this liability is best imposed. Finally, it will examine the factual settings of two seminal cases in food and drug law using the proposed guidelines.

The FDCA allows for the imposition of criminal sanctions against a corporation itself and against officers and employees of that corporation. Section 303 of the Act states that [any person who violates the Act is subject to criminal fines, imprisonment, or both.⁴ The Act defines person elsewhere as an individual, partnership, corporation, and association.⁵ However, the statute left unclear the question of whether the relevant person can at the same time be both a corporation and

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the individual officers or employees who act on behalf of the corporation.

The Supreme Court, in two decisions separated by thirty years, clarified the statutory ambiguity. In United States v. Dotterweich,⁶ the Court held that under the FDCA a corporation may commit an offense and all persons who aid and abet its commission are equally guilty.⁷ Such persons include all who do have such a responsible share in the furtherance of the transaction which the statute outlaws.⁸ FDCA criminal liability, moreover, is a form of strict criminal liability; the government need not offer any proof of the criminal intent of those who stand in such a responsible relation.⁹ Left undefined by the Dotterweich court was the precise meaning of responsible relation.

Seeking to clarify the meaning of responsible relation, the Court in United States v. Park¹⁰ held that the government establishes a prima facie case of criminal liability when it presents facts that a defendant's position in the corporation would have allowed that defendant to prevent the criminal violation in the first instance or correct the criminal violation once discovered. The Park Court also sought to limit the scope of criminal liability by excusing corporate officers when preventing or correcting the criminal violation would be objectively impossible.¹²

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As interpreted by the Supreme Court, then, criminal liability under the FDCA is potentially boundless. The government may prosecute not only the corporation itself, but also any officer or employee who exercises some measure of authority over the relevant corporate activities. Seemingly, the only limit to the sweep of FDCA criminal liability is the discretion afforded the FDA, by legislative enactment³ and by judicial opinion,⁴ to initiate – or refuse to initiate – criminal proceedings .

With respect to the decision to initiate criminal proceedings against corporate officers or employees, current FDA policy is informal at best, irrational at worst. No codified

regulations govern the decision. And, unlike the decision to

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either

initiate criminal proceedings against a corporation, n

do internal policy guidelines. Instead, the FDA focuses its analysis on whom to prosecute, not whether prosecution is warranted in the first place. The FDA policy is simply to include at least one corporate officer or employee as a defendant.⁷ The rationale is that criminal sanctioning is ineffective as a deterrent unless it falls on the individuals who constitute the corporation, and not just the legal entity that is the corporation. The only issue left for determination, then, is which corporate officer or employee the FDA wishes to charge. Generally speaking, the FDA, with a glance at the Park decision,

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chooses only those officers or employees in a position to prevent the violation or correct the violation once it became known. And, the FDA will only seek prosecution if, after being advised of the violation, the corporate officers or employees fail to correct it.¹⁹

The FDA reviews the decision to prosecute an individual at a number of bureaucratic levels within the agency - - both at the regional offices and at the headquarters. At each level, FDA officials give the decision careful consideration to ensure it conforms with FDA policy.²⁰ Prior to final disposition within the agency, the FDA notifies the corporate officer or employee of its impending decision and affords him the opportunity for a hearing before the FDA. The notice and hearing procedures, codified in regulation, **21** are termed Section 305 hearings, after the statutory provision requiring them.²² The hearing process is largely informal²³ and the corporate officer or employee need not appear, though it is an important opportunity to convince the FDA that criminal prosecution is unwarranted.²⁴ Recent practice has been to institute Section 305 hearings only when the FDA has already decided that prosecution is likely to be appropriate; the hearings are not to be considered warnings.²⁵

FDA policy always to include at least one corporate officer or employee as a defendant demands critical analysis. Blind adherence to the policy is unjustified and largely inefficient.

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Discretion to initiate criminal proceedings must be exercised with caution. Criminal proceedings and criminal punishment, like the criminal violations they are designed to prevent, are socially costly.²⁶ It makes little sense to incur these significant costs unless significant benefits result. Necessary, then, is an analytical framework to guide the FDA into initiating criminal proceedings only when they generate net social benefits. Applying economic tools to FDA decisionmaking in this area – a practical, logically sound, and convenient approach – would ensure net social benefits.

An economic analysis can serve to guide the FDA in reaching its most important decisions concerning criminal liability for corporate officers or employees. First, economic analysis will help FDA set optimal levels for criminal sanctions. Next, economic analysis will help FDA determine whether it should initiate proceedings against the corporate officers or employees. Finally, economic analysis will establish when fines constitute suitable sanctions and when imprisonment is necessary.

In economic terms, an optimal level for criminal sanctions is one that achieves the greatest benefit at the least cost. To begin the analysis, assume for simplicity that the benefit to be derived from criminal sanctioning is the prevention of FDCA violations. This is a fair assumption given that the explicit purpose of imposing criminal sanctions against FDCA violators is

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to prevent the violations in the first instance.²⁷ Next, assume that a potential violator of the FDCA exhibits economically rational behavior. In other words, the violator will act only when the expected benefits for him of violating the FDCA exceed the expected costs. **28** This, too, is a fair assumption given that the potential violators of the FDCA generally are corporations or corporate officers or employees whose primary motive is profit maximization.

Given these two assumptions, it is clear that an optimal level of criminal sanction from the standpoint of the FDA is one that would make it too costly for the potential violator to

29 other so that
act. In words, the sanction must be set the
expected costs for the potential violator of violating the FDCA exceed the potential benefits. In such circumstances, the economically rational potential violator will choose not to violate the FDCA, as he expects that he will be better off not violating the FDCA than violating it.

The optimal level of criminal sanction will depend upon the ex ante probability of the FDA's catching and successfully prosecuting the potential violator. By definition, the expected costs for the potential violator can be calculated by multiplying the probability of facing the sanction by the sanction itself. To use a numerical example, assume that the sanction for violating the FDCA is \$1,000. Assume further that the FDA

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catches and successfully prosecutes violators only 10% of the time. In such a case, the potential violator can expect that he will face a \$100 fine if he chooses to act, since he knows that the \$1,000 sanction will be imposed only one in ten times. There are an infinite number of combinations of sanction and probability whereby the potential violator faces the same expected \$100 fine. For instance, if the sanction were set at \$2,000, the probability need only be set at 5% for the expected fine to be \$100. Similarly, if the sanction were set at \$500, the probability need be set at 20% for the expected fine to be \$100.

Given the infinite number of combinations of sanction and probability available, the FDA, were it to act rationally, would choose to set the sanction relatively high and the probability relatively low. Assume for the moment that imposing a sanction is a costless process.³⁰ Recall, however, that catching and prosecuting a violator involve great costs. A rational actor would seek to minimize these costs without sacrificing the benefits of enforcement.³¹ To do so, the actor, in this case the FDA, would determine the minimum expected cost necessary to deter a potential violator, and then set the sanction high enough so that it need not expend significant resources catching and prosecuting violators.³² To see this numerically, assume that the benefits a potential violator will receive from violating the

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FDCA are \$99. The FDA would need to set the sanction and the probability so that the potential violator would face a \$100 fine should he choose to act. The FDA could, for example, choose among the following combinations of sanction and probability, respectively: \$100, 100%; \$1,000, 10%; \$10,000, 1%. The potential violator would be indifferent to these choices; in all cases, he expects to pay a \$100 fine. For the FDA, however, the third choice is best; it spends the least amount of money yet achieves the same result.³³

The difficulties presented by such an inquiry are obvious; they suggest an important shortcoming in the analysis. In order to determine the optimal level of sanction and probability, the government would need, first, information as to the benefits a potential violator would expect from an FDCA violation. Such information is theoretically available, but prohibitively costly. The cheapest means of acquiring such information would be from the potential violator himself. But, this approach defeats the purpose of the sanction because it identifies violators *ex post* and fails to prevent violations *ex ante*. Even assuming the FDA could gather the information, it would need to determine how different levels of expenditures of enforcement resources would affect the probability of catching and successfully prosecuting potential violators. The determination would be inexact at best.

The described difficulties are damaging to the analysis, but

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not fatal. One possible means of addressing them is to set a very high sanction and prosecute a widely known offender. Such a course is advisable because it maximizes expected sanctions without imposing significant costs on the FDA. A highly public prosecution may skew the perception of other potential violators as to the probability of their later being caught and successfully prosecuted. Coupled with the extremely high sanction, the misperceived probability leads to a high expected cost. This should deter most potential violators. Such a course, however, is fraught with risk. First, too high a sanction may be socially unacceptable as not commensurate with the violation. Next, choosing the defendant based on public relations value is problematic from a fairness standpoint. Finally, the other potential violators may not be fooled by the gambit.

As can be derived from the foregoing analysis, the difficulties notwithstanding, the appropriate defendant in a criminal case will be the person or persons who both can choose the violation and will benefit from the violation. Imposing a criminal sanction on a defendant who cannot choose the violation would be wasteful.³⁵ Such a defendant would, by definition, act whether or not he expects the cost of the sanction to be imposed on him. As for the defendant who does not benefit from the violation, there is no incentive for him to act in the first

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instance; he stands to gain nothing from the violation, but will expect a cost. Again, the imposition of a criminal sanction on such a defendant would be wasteful, as there is no need to prevent him from committing a violation.

In a typical case of an FDCA violation, the corporation itself and any number of corporate officers or employees both can choose³⁶ the violation and will benefit³⁷ from the violation. **38** According to the model described above, then, both the corporation and the relevant officers or employees should face the cost of criminal sanctions. However, because of the existence of disciplining mechanisms within corporations, it may not be optimal to impose criminal liability on corporate officers or employees. Instead, the FDA may choose to allow the corporations to punish the officers or employees in their own ways.

The FDA should forego criminal prosecution of corporate officers or employees when the disciplining mechanism within a corporation imposes an optimal sanction³⁹ on an officer or employee more cheaply than the FDA can impose its own, presumably optimal, sanction. **40** In fact, the FDA is already encouraging closer monitoring and more stringent sanctioning within corporations. In so doing, the FDA will be able to minimize enforcement costs without sacrificing result. Generally speaking, it is relatively cheap for a corporation to initiate

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disciplinary proceedings against an officer or employee because the corporation is not burdened with the requirements of due process.⁴² However, economies of scale produce savings when the government investigates and imposes sanctions against both the corporation and its officers or employees in one proceeding; a second proceeding initiated by the corporation could be duplicative and therefore wasteful.⁴³ It might be that the savings achieved outweigh the cost of due process, arguing for government, as opposed to corporate, sanctioning.

That the result will be the same from the perspective of the corporate officer or employee, whether he faces sanctions from the FDA or the corporation, is clear. Like the FDA, the corporation, because it faces sanctions for FDCA violations, wishes to prevent its officers or employees from committing violations. To do so, it will set its own internal sanctions so that the expected costs for its officers or employees of violating the FDCA will exceed the expected benefits. As a rational actor, the corporation will reach the same conclusions about optimal sanctioning, described above, the FDA would reach.⁴⁵ In either case, then, the corporate officer contemplating an FDCA violation will face expected costs exceeding expected benefits.

As with the analysis of sanctioning, the analysis of the appropriate defendant has shortcomings. The most obvious is the

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information cost involved in assessing a corporation's internal disciplining mechanism. The first cost associated with the analysis is determining whether the corporation has an effective mechanism at all. Perhaps the only source of such information is the very defendant, the officer or employee, the FDA is considering prosecuting. And, these officers and employees have a sharp incentive to exaggerate the usefulness of the disciplining mechanism in order to avoid criminal liability. The next cost is determining how efficiently such a mechanism operates. Again, there seems to be no unbiased source of such information. As above, however, the difficulties described are not fatal to the analysis. A possible solution is for the FDA to consider the past history of the corporation and its responses to criminal proceedings brought against it. Such information might surface during Section 305 hearings. Presumably, the corporation, to appease its shareholders or improve public relations, would have instituted disciplining mechanisms following previous criminal proceedings. If it did not, or if there were no previous criminal proceedings, the FDA should simply initiate an action against the relevant officer or employee on the assumption that only the FDA is in a position to impose an optimal sanction.

Seeking to minimize enforcement costs extends to the FDA decision of whether to impose monetary or nonmonetary sanctions

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on a violator. From the FDA perspective, these sanctions are equally effective. In other words, it is possible to place a monetary value on a nonmonetary sanction so that a potential violator would be indifferent as to which sanction the FDA imposed. For example, assume that one hour in jail is worth \$100 to a potential violator. From the perspective of the potential violator, then, it makes no difference whether the sanction for the violation is five days in jail or \$12,000.⁴⁶ For him, the sanction is the same. Therefore, the deterrent effect is the same. From the perspective of the FDA, however, the two sanctions present a stark choice. On the one hand, monetary sanctions, relatively cheap to impose, provide revenue for the government; on the other, nonmonetary sanctions, relatively expensive to impose, drain revenue from the government.⁴⁸ Therefore, to minimize enforcement costs without sacrificing result, the FDA should choose to impose fines as a first option, and resort to prison only when necessary.

Two interrelated factual issues determine whether prison is an appropriate sanction for a corporate officer or employee:

the wealth of the officer or employee and the likelihood that a violation will be difficult to detect. The wealth of the officer or employee sets the maximum monetary sanction the FDA could impose on that officer or employee. Any sanction beyond the maximum will simply never be paid. In such circumstances, the

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officer or employee will not face the optimal expected costs because he faces sanctions equal to his wealth, not the optimally chosen sanction. For example, assume that the optimal expected cost to deter an expected benefit of \$99 is \$100, where the probability of being caught is 10% and the sanction is \$1,000. Assume also that the officer's or employee's wealth is \$900. The officer or employee will face an expected cost of only \$90 – a 10% chance of losing his \$900 in wealth. Therefore, the officer or employee will choose to commit the violation here, as the expected benefit exceeds the expected cost. To make up for the \$100 difference in sanctions, the FDA may simply impose the equivalent of \$100 worth of prison. Then, the officer will face the optimally chosen sanction.

When a violation is difficult to detect, it is likely that the optimal sanction will be extremely high, increasing the prospect of its exceeding the officer's or employee's wealth and leading to a prison sanction. By definition, the probability that the FDA will catch and successfully prosecute a potential violator when the violation is difficult to detect is small. As noted above, when the probability of prosecution is small, the sanction must be high so that the potential violator faces optimal expected costs.⁵¹ An extremely high sanction will doubtlessly exceed the officer's or employee's wealth, leading the FDA to seek a prison term.⁵² Therefore, when the violation

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is easily concealed, the FDA should seek nonmonetary sanctions. This part of the analysis suffers, too, from potential

drawbacks. Again, information costs are the most obvious of those drawbacks. A frequent, and fair, criticism of the approach raises the concern that it is difficult to assign monetary values to nonmonetary sanctions, especially when potential violators value nonmonetary sanctions differently. Nonetheless, it is both theoretically possible and currently employed. Consider, for instance, a criminal statute the violation of which carries a 30-day prison term or a \$5,000 fine. The drafters of the statute presumably believed that a 30-day prison term is roughly equivalent to \$5,000.

To pause for a summary, then, the above analysis recommends the following guidelines for FDA discretion. First, the FDA should set sanctions so that the expected costs for a potential FDCA violator exceed his expected benefits. Next, the FDA should seek criminal sanctions against a corporate officer or employee when he could choose and would benefit from the violation, and when internal corporate disciplining procedures are either nonexistent, non-functioning, or relatively inefficient. Finally, the FDA should seek prison terms only when a defendant cannot fully pay the assessed fine. To see how the suggested guidelines might work, it will be helpful to apply them to specific facts. The Dotterweich and Park cases serve as

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convenient factual settings here.

The Dotterweich case is particularly interesting. Dotterweich was president and general manager of Buffalo Pharmacal Company, a small business that purchased drugs from wholesalers and resold them to physicians.⁵³ Learning of Buffalo Pharmacal's misbranding of a number of shipments of drugs, the government sought to impose criminal sanctions on both the corporation and Dotterweich.⁵⁴ Somewhat surprisingly, at trial the jury acquitted the corporation but convicted Dotterweich.

Because of the difficulties in determining optimal levels of sanction and probability, as explained above, the first factor I will examine is whether Dotterweich had the opportunity to choose the violation. While he may have had no personal knowledge of the misbranding, Dotterweich was in a position to establish procedures to ensure that the misbranding would not occur. Only twenty six employees, all located on one floor of a building, worked for Buffalo Pharmacal.⁵⁶ Presumably, Dotterweich could exercise significant day-to-day and transaction-by-transaction supervisory control over all twenty six employees. Were he concerned about the possibility of misbranding, he could have exercised that control more carefully. In a sense, then, Dotterweich chose the violation by not exercising this control.

The next factor to consider is whether Dotterweich

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benefitted from the violations. The facts of the case suggest only that the misbranding was inadvertent. It is not clear, then, that any benefit accrued to Dotterweich, or, for that matter, to the corporation. However, one could rightly argue that the corporation saved a significant amount of money by choosing not to institute appropriate supervisory control. In that sense, then, the corporation benefitted from the violation. Further, Dotterweich could be seen to have benefitted, though indirectly. His choice to avoid the supervisory controls and save the corporation money could have brought him salary increases, job security, or the like.

The next question to consider is whether Buffalo Pharmacal had in place internal monitoring procedures such that Dotterweich would face corporate disciplinary proceedings. Although the facts as reported do not supply the answer, a few assumptions may be warranted. First, the small size of the corporation and its seemingly informal nature suggest that no internal mechanisms were in place. And, it is clear that Dotterweich exercised great control within the company. Even if internal mechanisms existed, it is not likely that they would be utilized to discipline Dotterweich.

Given that Dotterweich chose the violation, benefitted from it, and likely would not face sanctions from the corporation, the government was correct in bringing charges against him. The

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decision to seek a monetary, as opposed to nonmonetary, sanction must now be examined.

Assuming that the government set the level of the fine optimally, prison would be inappropriate in this case. The fines totalled **\$j,5QQ•57** Although not a trivial sum in 1942, Dotterweich could probably afford it. Therefore, resort to nonmonetary sanctioning would be unnecessary.

Moreover, concealing the misbranding of drugs is difficult. If the drugs caused harm, the harm - illness or death - would likely be significant. Government authorities would normally learn of that harm - from the victims, their families, or their doctors - and seek to determine its cause. If the drugs did not cause harm, any random testing of the drugs would reveal the misbranding. As noted above, when a violation is difficult to conceal, there is no need for extremely high sanctions because the likelihood of successfully catching and prosecuting violators is high. Without extremely high sanctions, resort to non-monetary sanctioning would be unnecessary.

The different factual setting of the Park case leads to a somewhat different conclusion as to the advisability of initiating criminal proceedings against Park. Park was president and chief executive officer of Acme Markets, a large, national retail food chain.⁵⁸ After finding evidence of rodent infestation at a number of Acme warehouses and alerting Park to

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the problem, the government sought to impose criminal sanctions against the corporation and against Park.⁵⁹ Acme pled guilty to the charges; a jury found Park guilty and fined him a total of

\$250 60

Unlike Dotterweich, Park knew about the rodent infestation problem. On a number of occasions, the government informed Park by letter of the infestation.⁶¹ Park attempted to correct the problem, but failed. In failing, one could certainly argue that Park chose to allow the violations to occur. He simply did not do enough to end them.

Again, unlike Dotterweich, Park probably did not benefit from the violations. Instituting a more effective system to monitor warehouse sanitation than that existing when the violations occurred would presumably be expensive. Failing to do so likely saved Acme some money. However, it is not clear that such savings would, in the context of such a large corporate endeavor, be significant. If the savings were, in fact, insignificant, then benefit to Park in the form of salary increases, job security, or the like would be small or nonexistent. Even if the savings were significant, prosecution of Park may still not be warranted. In the sprawling enterprise that is Acme, benefit to the corporation would not accrue to the employees to the same degree as would benefit in a smaller operation, such as Buffalo Pharmacal. The link between corporate

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performance and employee benefit may be too attenuated. Also unlike Dotterweich, Park likely would face a well-

established corporate mechanism for ensuring internal discipline, operated either by the outside board of directors or the inside management. Although the facts of the case do not speak of any such mechanism, it is fair to assume that a complex business operation like Acme has in place such a formal mechanism. It would be hard to imagine Acme's being able to function without

it. However, more investigation would be necessary, especially as to the relative cost of instituting internal disciplinary proceedings and the level of sanctions Park might expect from the corporation.

Although Park chose the violation, he may not have benefitted from it and, regardless of the government's decision to act, may face sanction from Acme itself. Therefore, it is far from clear that the government appropriately chose to initiate criminal proceedings against Park. Assuming, however, that the decision was appropriate, the next step is to examine whether monetary sanctions would suffice.

Assuming the government set the sanction optimally, nonmonetary sanctions would be unnecessary. The fines totalled \$250, hardly a severe burden for the president of such a large corporation and unlikely to lead to his bankruptcy.

However, because the violations in this case are more easily

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concealed than those in Dotterweich, nonmonetary sanctioning may be appropriate. Rodent infestation, unlike misbranding of drugs, does not raise the specter of severe harm. Even if harmed in fact, the victims may not be aware of the harm. Moreover, there is not necessarily an easy, foolproof means of inspecting a warehouse for rodent infestation. An inspector may simply miss the evidence of infestation. Because the violations may be relatively easy to conceal, higher sanctions may be appropriate. In other words, the previous assumption that \$250 is a correct sanction may be misplaced. And, with higher sanctions comes the higher probability of requiring the imposition of nonmonetary sanctions **62**

In conclusion, the guidelines suggested by the paper are far from perfect, but important nonetheless. Certainly the guidelines would be difficult to implement with any precision. However, the guidelines would provide the FDA enforcement officer with a roadmap to help him maneuver through the difficult decision as to whether it is appropriate to initiate criminal proceedings against a corporate officer or employee. In other words, the guidelines are not intended to provide the FDA with the right answers, but with the right questions.

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1. 21 U.S.C. §§ 301 - 395 (1988 & Supp. V 1993)

2. See Carol Benjamin & Betsy J. Floman, Federal Food and Drug Act Violations, 31 Am. Crim. L. Rev. 629, 643 (1994)

3. The problem of costly, inefficient, and unnecessary criminal prosecutions is less acute in cases of individual liability outside the corporate context and in cases of liability for partnerships. Unlike cases of corporate liability, such cases do not normally present the FDA with the occasion to prosecute both a business entity and an individual separately.

4. 21 U.S.C. § 333(a) (1) (1988)

5. Id. § 321(e)

6. 320 U.S. 277 (1943)

7. Id. at 284.

8. Id.

9. See id. at 284 - 85.

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10. 421 U.S. 658 (1975)

11. See id. at 673 - 74.

12. See id. at 673.

13. See 21 U.S.C. § 336 (Nothing in [the FDCA] shall be construed as requiring the Secretary to report for prosecution, or for the institution of libel or injunction proceedings, minor violations of this Act whenever he believes that the public interest will be adequately served by a suitable written notice or warning.)

14. See. e.c. Heckler v. Chaney, 470 U.S. 821, 835 (1985) (The (FDCA's] enforcement provisions thus commit complete discretion to the Secretary to decide how and when they should be exercised.)

15. Ultimately, the decision to proceed with a prosecution lies with the Department of Justice (DoJ). This paper is solely concerned with the FDA decision to recommend to the DoJ a course of action. It is not concerned with decisionmaking at the DoJ.

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16. The decision to bring suit against a corporation is governed by a thoughtfully conceived analysis of the costs and benefits of initiating the action. ~ Yiu H. Hui, United States Food Laws, Regulations, and Standards 482 - 87 (1979); Sam D. Fine, The Philosophy of Enforcement, 31 Food Drug Cosm. L.J. 324, passim (1976); Eugene M. Pfeifer, Section 305 Hearings and Criminal Prosecutions, 31 Food Drug Cosm. L.J. 376, passim (1976)
17. See Richard A. Merrill, The Park Case, 30 Food Drug Cosm. L.J. 683, 685 (1975)
18. See id.
19. See id.
20. See Hui, supra note 16, at 484 - 87.
21. See 21 C.F.R. §§ 7.84 - 7.87 (1994).
22. See 21 U.S.C. § 335 (1988) (codifying § 305 of the original FDCA).
23. See 21 C.F.R. § 7.85(c) (1994).

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24. See id. § 7.84(f).
25. See Fine, su^{ra} note 16, at 326.
26. Little would be gained by highlighting statistics detailing the cost of the criminal justice system in the United States. Suffice it to say that preventing crime is a costly venture.
27. See 1 James T. O'Reilly, Food and Drug Administration § 8.01, at 8-3 (2nd ed. 1994).
28. See Richard A. Posner, Economic Analysis of Law 223 (4th ed. 1992). Because the FDA seeks to affect a potential violator's actions ex ante, the analysis turns on expected benefits and costs.
29. See id. at 224.
30. The costs associated with imposing a sanction will be discussed in the text briefly below.
31. See Posner, supra note 28, at 225.

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32. For simplicity, the discussion is assuming a risk neutral actor. The analysis would be slightly different were the actor risk averse or risk loving. The general idea, however, is the same.

33. Note that there probably is a limit to the level of sanction the FDA could impose. It is likely that beyond a certain point, society would protest that the penalty is not commensurate with the crime. Such a protest, though it may be morally justified, is not necessarily economically rational.

34. The FDA, in fact, is taking this approach. See Benjamin & Floman, su~ra note 2, at 641 - 45 (describing FDA enforcement against widely known companies and products, such as Procter & Gamble and Beech-Nut Nutrition)

35. By wasteful, I mean that the imposition of the sanction will impose a social cost but will garner no social benefit.

36. Naturally, that the corporation is choosing is a fiction, but no more a fiction than its legal existence as a person.

37. Corporate officers possibly benefit from FDCA violations in at least two ways. First, such violations may increase corporate

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profits, to which salaries may be tied. Second, increasing profits may lead to promotions or increased job security.

38. Certainly, there may be instances where only the corporation or only its officers or employees both can choose the violation and will benefit from the violation. Because such cases seem rare, however, I will ignore them for simplicity.

39. An optimal penalty is assumed here to be the same as that described above. See supra text accompanying notes 27 - 33.

40. Because there does not exist a private right of action to enforce the FDCA, **see Peter B. Hutt & Richard A. Merrill, Food and Drug Law** 1217 - 19 (2nd. ed. 1991) (discussing cases holding that the FDCA does not give rise to a private right of action in federal court), and because there is likely no private mechanism to discipline corporations, the FDA should always initiate criminal proceedings against the corporation. Theoretically, trade associations could discipline members for FDCA violations. However, antitrust law would severely limit such sanctions, leaving the trade associations all but powerless in this regard.

41. See 1 **O'Reilly, supra** note 27, § 8.02, at 8-9. The dissent in Dotterweich suggested a similar course. Justice Murphy

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proposed that the corporation could bring suit against the relevant officers or employees for breaching their duties to the corporation. See United States v. Dotterweich, 320 U.S. 277, 286 (1943) (Murphy, J., dissenting) . However, this is not the type of internal monitoring the text advocates. A suit initiated by the corporation against its officers or employees is likely to be only slightly less costly than a criminal suit brought by the government against the same officers or employees. And, because of the difficulty in bringing such suits from the shareholders' perspective, they would be rare.

42. See John C. Coffee, Jr., No Soul to Damn: No Body to Kick: An Unscandalized Inquiry Into the Problem of Corporate Punishment, 79 **Mich. L. Rev.** 386, 408 (1981)

43. See *id.*, at 387 & n.6.

44. Presumably, the sanctions will be set so that the corporation will never choose to violate the FDCA; in other words, the sanctions will be optimal, as described above. See *su~ra* text accompanying notes 27 - 33. Should the sanctions be nonoptimal, the corporation may be encouraged to violate the FDCA. In that case, the argument in the text fails; the corporation would not set any sanctions for its officers or

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employees because a decision to violate the act will benefit, not harm, the corporation. In fact, the corporation may create incentives for its officers or employees to violate the FDCA.

45. Note, too, that the problem of determining the optimal combination of sanction and probability is mitigated when a corporation imposes the penalty. The corporation is better positioned than the FDA to determine the optimal combination because it is closer to the potential violator and is likely already monitoring the potential violator in some fashion.

46. Each day is worth \$2,400 (24 hours multiplied by \$100 per hour). So, five days is worth \$12,000 (5 days multiplied by \$2,400 per day)

47. Generally speaking, more stringent procedural protections attach to government proceedings imposing prison terms than to those imposing fines.

48. See Posner, *supra* note 28, at 227. Consider especially the costs of running a prison system.

49. Obviously, the FDA cannot jail a corporation.

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50. Note that the problem of wealth cannot be cured by imprisonment when the defendant is the corporation. See Coffee, supra note 42, at 389 - 93.
51. See su~ra text accompanying notes 27 - 33.
52. See su~ra text accompanying notes 49 - 50.
53. See United States v. Buffalo Pharmacal Co., 131 F.2d 500, 501 (1942)
54. See id.
55. See id. The defense attorney seemed to have convinced the jurors that convicting the corporation would put all of its employees out of work. See Hui, su~ra note 16, at 488.
56. See United States v. Park, 499 F.2d 839, 841 n.3 (1974)
57. See Buffalo Pharmacal, 131 F.2d at 501.
58. See United States v. Park, 421 U.S. 658, 660 (1975)
59. See id.

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60. United States v. Park, 499 F.2d 839, 840 (1974)

61. See Park, 421 U.S. at 662, 664.

62. A likely reaction to the conclusion that nonmonetary sanctions might be appropriate for Park but not for Dotterweich is one of confusion. It may seem counterintuitive to seek prison sanctions for violations that may lead to relatively minor harm, but not seek prison sanctions for violations that may lead to relatively major harm. In fact, such a course is rational, given the assumption that the purpose of the sanctions is not to punish for the sake of punishment but to prevent violations in the first place. It simply may be that achieving that goal in the most efficient manner possible requires counterintuitive, but economically rational, measures.