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CRIMINAL PROSECUTIONS INITIATED BY ADMINISTRATIVE AGENCIES: THE FDA, THE *ACCARDI* DOCTRINE AND THE REQUIREMENT OF CONSISTENT AGENCY TREATMENT*

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On November 5, 1986, a federal grand jury in Brooklyn, New York, returned a 470-count indictment against Beech-Nut Nutrition Corporation ("Beech-Nut"), the nation's second-largest manufacturer of baby food products, on charges of marketing adulterated and misbranded apple juice for babies.[1] Also named as defendants in the indictment were Beech-Nut's president and chief executive officer, its vice president, and four other individuals. The indictment resulted from an investigation by the Food and Drug Administration ("FDA") which apparently convinced FDA officials to refer the matter to the United States Attorney's Office for criminal prosecution.

The Beech-Nut case illustrates the important and often overlooked role that administrative agencies play in the criminal enforcement of federal statutes.[2] The FDA is one of numerous federal

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1 Washington Post, Nov. 6, 1986, at B9, col. 1. The indictment included one conspiracy count, 20 counts alleging mail fraud and 449 counts alleging violations of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 (1982 & Supp. III 1985).

2 The principles discussed herein, however, do not necessarily apply to the Beech-Nut case. The authors have cited Beech-Nut merely as a recent and highly publicized example of the critical role that administrative agencies often play in the criminal enforcement of federal laws. On the other hand, news reports suggest that Beech-Nut might argue that it did not know that its apple juice was adulterated and misbranded.

agencies that has the authority to recommend criminal prosecution for violations of the statutes and regulations that it administers.[3] This Article discusses the procedural and substantive legal issues that arise when companies and individuals are so prosecuted.[4] For illustrative purposes, this Article refers to a hypothetical situation in which the FDA is considering criminal prosecution of a corporate officer in a routine case, even though the officer has received no prior warnings from the FDA regarding the specific violations for which prosecution is being considered. "Routine" cases are those cases which do not involve a "health hazard, fraud or extremely gross violations."[5] Such a prosecution would be inconsistent with the FDA's policy of not recommending criminal prosecution in routine cases unless a party has first been given a warning and an opportunity to remedy the alleged violation.[6]

This Article also considers the applicability of the limitations imposed upon agencies by the so-called *Accardi* doctrine[7] and by the separate but related requirement of consistent treatment of regu-

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Lack of knowledge, in and of itself, is no defense to an alleged violation of the Federal Food, Drug and Cosmetic Act. *See* 21 U.S.C. §§ 331, 333 (1982 & Supp. III 1985). For reasons stated in this Article, however, Beech-Nut and its corporate officials might be able to raise the related, but distinct, defense of lack of prior notice. It is to this extent that this Article is relevant to the Beech-Nut case.

[3] *See, e.g.*, 2 U.S.C. § 437g(a)-(d) (1982)(Federal Election Commission); 15 U.S.C. § 68h, 69i(b) (1982)(Federal Trade Commission); 15 U.S.C. § 77t(b), 78u(d) (1982)(Securities and Exchange Commission); 15 U.S.C. § 717s(a) (1982)(Federal Energy Regulatory Commission). Absent a statutory provision to the contrary, a referral from the appropriate federal agency is not a prerequisite to prosecution by the Department of Justice. *See* United States v. Morgan, 222 U.S. 274, 281 (1911)("[I]f, for any reason, the executive department failed to report violations of [the Pure Food and Drug Act], its neglect would leave untouched the duty of the district attorney to prosecute 'all delinquents for crimes and offenses cognizable under the authority of the United States.' "); United States v. Int'l Union of Operating Engineers, Local 701, 638 F.2d 1161, 1163 (9th Cir. 1979), *cert. denied*, 444 U.S. 1077 (1980); United States v. Tonry, 433 F. Supp. 620, 622-23 (E.D. La. 1977).

[4] Other articles of related interest include: Brickey, *Corporate Criminal Liability: A Primer For Corporate Counsel*, 40 BUS. LAW. 129 (1984); Frase, *The Decision to File Federal Criminal Charges: A Quantitative Study of Prosecutorial Discretion*, 47 U. CHI. L. REV. 246 (1980); McConachie, *The Role of the Department of Justice in Enforcing the Federal Food, Drug and Cosmetic Act*, 31 FOOD DRUG COSM. L.J. 333 (1976); Morris, *Environmental Problems and the Use of Criminal Sanctions*, 7 LAND & WATER L. REV. 421 (1972); Rabin, *Agency Criminal Referrals in the Federal System: An Empirical Study of Prosecutorial Discretion*, 24 STAN. L. REV. 1036 (1972); *Developments in the Law—Corporate Crime: Regulating Corporate Behavior Through Criminal Sanctions*, 92 HARV. L. REV. 1227, 1307-11 (1979)[hereinafter cited as *Corporate Crime*]; Wheeler, *Potential for Criminal Liability of Personnel Under Federal Acts*, Nat'l L.J., Mar. 24, 1986, at 22. *See also* K. DAVIS, DISCRETIONARY JUSTICE (1969).

[5] *See infra* note 24 and accompanying text.

[6] *See infra* notes 21-29 and accompanying text.

[7] *See infra* notes 80-131 and accompanying text.

lated entities by agencies.[8] It is argued that both limitations should apply with full force to agency decisions involving criminal prosecutions. When criminal sanctions are a possibility, courts should be particularly vigorous in ensuring that agencies do not exercise their discretionary authority in an arbitrary, capricious or inconsistent manner.

I. CRIMINAL PROSECUTIONS INITIATED BY THE FDA

The Food, Drug, and Cosmetic Act ("the Act")[9] authorizes the criminal prosecution of corporations and corporate individuals who perform certain "prohibited acts."[10] It is not, however, "a mandatory statute that requires the FDA to prosecute all violations of the Act. . . . [T]he FDA clearly has significant discretion to choose which alleged violations of the Act to prosecute."[11] The "Act charges the Secretary only with recommending prosecution; any criminal prosecution must be instituted by the Attorney General. The Act's enforcement provisions thus commit complete discretion to the [agency] to decide how and when they should be exercised."[12] Such "significant" and "complete" discretion creates

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8 *See infra* notes 72-79 and accompanying text.

9 21 U.S.C. § 301 (1982 & Supp. III 1985).

10 *Id.* §§ 331, 333. With limited exceptions, *see id.* at § 333(c)-(d), the Act is a "strict liability" statute as "knowledge or intent [are] not required to be proved in prosecutions under its criminal provisions . . . ." United States v. Park, 421 U.S. 658, 670 (1975). "[B]ut the Act, in its criminal aspect, does not require that which is objectively impossible." *Id.* at 673. To be held criminally liable, a person must have had "a responsible share in the furtherance of the transaction which the statute outlaws, namely, to put into the stream of interstate commerce adulterated or misbranded drugs." United States v. Dotterweich, 320 U.S. 277, 284 (1943). Moreover, "[t]he theory upon which responsible corporate agents are held criminally accountable for 'causing' violations of the Act permits a claim that a defendant was 'powerless' to prevent or correct the violation to 'be raised defensively at a trial on the merits.' " *Park*, 421 U.S. at 673 (quoting United States v. Wiesenfeld Warehouse Co., 376 U.S. 86, 91 (1964)).

11 Heckler v. Chaney, 470 U.S. 821, 842 (1985)(Marshall, J., concurring). The Court held in *Chaney* that the FDA's "decision *not* to take enforcement action" was "immune from judicial review." *Id.* at 832 (emphasis added). See *infra* notes 37-43, 117-25 and accompanying text for a discussion of *Chaney*.

12 *Chaney*, 470 U.S. at 835. *See also* Merrell Dow Pharmaceuticals, Inc. v. Thompson, 106 S. Ct. 3229, 3244-45 (1986)(Brennan, J., dissenting)(describing the "enforcement scheme established by the FDCA"); United States v. Kordel, 397 U.S. 1 (1970)(discussing issues raised by the simultaneous pursuit of civil and criminal actions by the FDA). The relevant decision-making chain for criminal enforcement actions under the Act is as follows:

> First, an inspector completes an establishment inspection report ("EIR").
>
> Second, the inspector's supervisor in the district office [initiates] the recommendation process for bringing action against the firm.
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> Third, the district compliance officer (who supervises enforcement case selec-

the strong possibility for abuse and inconsistency,[13] and, accordingly, the need for rigorous and effective judicial controls exists.

This Article considers possible legal impediments[14] to criminal

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tion and follow-up actions) must give approval after a review of the recommendation . . . .

Fourth, the district director must approve the recommended action (for prosecutions . . . approval of the regional food and drug director is also needed).

Fifth, the bureau responsible for the product category receives the report in its compliance unit and . . . weed[s] out insufficient field recommendations, returning some for further development.

Sixth, the regulatory management staff of the Associate Commissioner for Regulatory Affairs . . . reviews [the recommendation] for appropriateness in the use of legal resources.

Seventh, the recommendation goes to the Deputy Chief Counsel for litigation in the office of Chief General Counsel.

Eighth, in criminal cases, the commissioner's office may review the prosecution under general oversight responsibilities.

Ninth, the Justice Department's Antitrust Division, Consumer Affairs Section, reviews criminal . . . cases.

Finally, the United States Attorney for the local area in which the violative goods or persons are located is requested to bring the case to court.

I J. O'REILLY, FOOD AND DRUG ADMINISTRATION § 2.04 at 2-9 to 2-10 (1979). "[T]he Justice Department has terminated approximately one-quarter of referred prosecution cases during recent years." *Id.* § 8.04 at 8-18 (citing Hoffman, *Enforcement Trends Under the Federal Food, Drug & Cosmetic Act—A View from the Outside*, 31 FOOD DRUG COSM. L.J. 338 (1976)). *See also* United States v. Gel Spice Inc., 773 F.2d 427, 429 (2d Cir. 1985)(describing FDA's decision-making chain for referring cases to a U.S. Attorney), *cert. denied*, 106 S. Ct. 804 (1986).

[13] *See Corporate Crime*, *supra* note 4, at 1308-11 (noting the "disparity of treatment" and "arbitrariness" that often results from the broad discretion given in agencies).

[14] The legal impediments are to be distinguished from the factual arguments that counsel should make at all review levels, including review by the United States Attorney. *See generally* W. Lockhart, Report on the Exercise of Discretion in Prosecution of Violations of the Food, Drug and Cosmetic Act (Oct. 10, 1975)(unpublished first draft of a report submitted to the Administrative Conference of the United States). The Report notes that in 1972 an average of seven or more months expired between the FDA's inspection and the referral of a case to the United States Attorney. *Id.* at 35. Professor Lockhart criticizes the prosecution process at length because of the inconsistent and conflicting policies that exist among and within the FDA, the Consumer Affairs Section of the Department of Justice, and the United States Attorney's Office. He also discusses numerous factual considerations that, at one or more stages, have entered into decisions not to prosecute. *See, e.g.*, *id.* at 60, 150 (non-prosecution of the individuals who are less responsible for the actions undergoing review); *id.* at 71-73 (non-prosecution of individuals who "have left the company or been demoted to less responsible positions subsequent to the violations"); *id.* at 75 (non-prosecution of individuals because of "poor health" or because they were "civic leader[s] of some prominence").

It is difficult to ascertain whether the lack of coordination and the inconsistent policies in the criminal enforcement of the Food, Drug and Cosmetic Act are representative of criminal enforcement at the federal level. At the very least, federal officials have made a concerted effort to provide standards, guidance and consistency in the criminal prosecution of bank officials. On April 2, 1985, Attorney General Edwin Meese, III, announced "the signing of an agreement between the Department of Justice, the Federal Bureau of Investigation and four federal banking regulatory agencies designed to improve the detection, investigation, and prosecution of bank fraud cases, particularly those involving criminal misconduct on the part of bank officers." Department of Justice

prosecution in routine cases in which a corporate or individual defendant has not first been warned of the alleged violations and given an opportunity to take remedial actions.[15] There are at least two reasons why criminal prosecution may be inappropriate in this situation.[16] First, prosecution might violate the *Accardi* doctrine, which posits that "[a]n agency of the government must scrupulously observe rules, regulations, or procedures which it has established."[17]

News Release, Apr. 2, 1985, at 1. A "principal objective" of this agreement was to provide "uniform referral procedures both for routine and significant cases," including the use of "a standard referral form for all four agencies." *Id.* at 3. The four signatory agencies were: the Comptroller of the Currency, the Federal Home Loan Bank Board, the Federal Reserve Board, and the Federal Deposit Insurance Corporation. *Id.* at 1. *See also* U.S. DEP'T OF JUSTICE, UNITED STATES ATTORNEY'S MANUAL § 9-40.539 (1985)("Policy Concerning Prosecution" of bank bribery and bank fraud cases); *Criminal Law Enforcement Against Bank Officials: Hearings Before the Subcomm. on Commerce, Consumer, and Monetary Affairs of the House Comm. on Government Operations*, 98th Cong., 1st Sess. (1983).

15 *See supra* notes 5-6 and accompanying text. The FDA's prior-warning policy is distinct from the "Section 305" hearing that the Act requires the FDA to provide. Section 305 states that "[b]efore any violation . . . is reported by the Secretary to any United States attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to the contemplated proceeding." 21 U.S.C. § 335. Despite the existence of this provision, the Supreme Court has held that a Section 305 hearing "is not a prerequisite to prosecution." *Dotterweich*, 320 U.S. at 279. *See also* United States v. J. Treffiletti & Sons, 496 F. Supp. 53, 56 (N.D.N.Y. 1980).

16 Additional legal arguments may be available in a given case. For example, an individual defendant may be able to argue that he did not hold a "responsible relation" to the alleged violation. *See Park*, 421 U.S. at 670-76; *Dotterweich*, 320 U.S. at 281-85; United States v. Torgian Laboratories, Inc., 577 F. Supp. 1514, 1530-31 (E.D.N.Y.) (president convicted because "he was the individual . . . who had overall and ultimate responsibility for all . . . operations" and "the responsibility and authority to implement measures to insure that contamination of [contact] lenses sterilized by the corporation did not occur"), *aff'd mem.*, 751 F.2d 373 (2d Cir. 1984); United States v. New England Grocers Supply Co., 488 F. Supp. 230, 233 (D. Mass. 1980)(reversing a magistrate's conviction of a corporation's president because "the magistrate applied the wrong legal standard . . . finding him guilty solely by reason of his position as president"); *see also* FDA REGULATORY PROCEDURES MANUAL pt. 8-50-20, at 15, 16 (1984)(instructing district compliance officers that, in recommending prosecution, "[i]t is not sufficient to state that the individual is president of the corporation and . . . [is] therefore responsible. Include facts which tend to show his power or authority to, or to have others, do such things as: make capital investments; repairs, etc., hire or fire officers, employees, consultants, etc., and assign or change duties and responsibilities within the organization"). A second possible defense is the "impossibility" defense, suggested in *Park* and recognized by the lower courts. *See Park*, 421 U.S. at 673; *Gel Spice Inc.*, 773 F.2d at 434-35; United States v. Y. Hata & Co., 535 F.2d 508, 511-12 (9th Cir.)(per curiam), *cert. denied*, 429 U.S. 828 (1976); United States v. Starr, 535 F.2d 512, 515 (9th Cir. 1976). The impossibility defense requires a defendant to show that, despite the exercise of "extraordinary care," he was unable to prevent violations of the Act. *New England Grocers*, 433 F. Supp. at 234.

17 United States v. Heffner, 420 F.2d 809, 811 (4th Cir. 1976)(interpreting Accardi v. Shaughnessy, 347 U.S. 260 (1954)). When an agency fails to follow its own rules,

Second, a decision by the FDA in a routine case to recommend the prosecution of a defendant who has not first been warned and given an opportunity to act would be arbitrary, capricious and an abuse of discretion because the FDA typically has not recommended prosecution of similarly situated parties in the past. This latter argument parallels the identical FDA policy that supports the *Accardi* argument. It is, however, a distinct argument which is grounded in the well-established principle that "[p]atently inconsistent application of agency standards to similar situations lacks rationality and is arbitrary" action prohibited under the arbitrary and capricious standard of the Administrative Procedure Act ("APA").[18]

Apart from the *Accardi* argument, which some courts say is based upon due process principles, constitutional challenges on either due process or equal protection grounds may also be available. These challenges, however, are not likely to succeed. As discussed below, no constitutional rights are implicated unless a United States Attorney decides to prosecute. The United States Attorney's Office has almost limitless discretion with regard to prosecution decisions.[19] Most cases, therefore, present neither the compelling facts nor the necessary legal predicates to invalidate a decision to prosecute on constitutional grounds.

II. THE FDA'S PRIOR-WARNING POLICY

In most cases, the FDA sends a "regulatory" letter,[20] an "information" letter or some other type of warning to a company or individual regarding suspected violations.[21] These letters implement

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regulations or procedures, "its action cannot stand and courts will strike it down." *Id.* The precise underpinnings of the *Accardi* doctrine are unclear. *See infra* note 83.

18 Contractors Transport Corp. v. United States, 537 F.2d 1160, 1162 (4th Cir. 1976).

19 *See infra* notes 51-54 and accompanying text.

20 "A regulatory letter is a blunt warning about alleged violations of the . . . Act, sent by the [FDA's] field or headquarters offices to firms or individuals thought to be responsible for the violation. The letters, officially called 'notices of adverse findings,' generally are sent following an unsatisfactory inspection . . . ." I J. O'REILLY, *supra* note 12, 6.02 at 6-4 through 6-5. *See also* FDA REGULATORY PROCEDURE MANUAL pt. 8-10-20, at 2 ("[regulatory] letters . . . are used primarily to effect prompt correction. They are also a way of providing prior warning and notice to responsible officials of possible civil or criminal actions").

21 Potential defendants should consider filing a Freedom of Information Act ("FOIA") request to fill any gaps in the FDA's interaction with a particular company or individual. In particular, potential defendants should attempt to obtain copies of all regulatory and information letters and a copy of the company Compliance Profile Record. The Compliance Profile Record is located at the FDA's district office and lists the firm's history of inspections and regulatory actions. The FDA, however, may refuse to release these materials because of the on-going investigation and enforcement proceed-

the FDA's stated policy of giving warnings prior to instituting enforcement actions in routine cases. This policy is set forth in numerous provisions of the FDA's Regulatory Procedures Manual,[22] including:

> When it is consistent with the public interest, it is FDA's policy to advise regulated firms of potentially violative products, practices or conditions, or of violations requiring correction; and to give firms an opportunity to make corrections voluntarily prior to initiating legal or administrative action.[23]
>
> . . . .
>
> Except in cases involving a health hazard, fraud or extremely gross violations, prior warning must have been given to the firm and each individual involved [before a Section 305 Notice is issued]. This prior warning may be in the form of conferences, previous meetings, letters or previous court actions. In instances where the prior warning was in the form of letters or [a] Section 305 Notice involving past violations, copies must have been directed to each individual to be cited.[24]

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ings. *See* 21 C.F.R. § 20.64 (1986)(specific exemption in FDA's FOIA provisions for "investigatory records compiled for law enforcement purposes").

22 Such a policy should not affect the relevant legal analysis under applicable precedent, *see, e.g.*, Morton v. Ruiz, 415 U.S. 199, 234-35 (1974); Massachusetts Fair Share v. Law Enforcement Assistance Administration, 758 F.2d 708, 711 (D.C. Cir. 1985), as these policy statements are not formal rules or regulations produced by rule-making or adjudication. *Cf.* 21 C.F.R. pt. 7 (1986)(entitled "Enforcement Policy," referencing its purpose of "assur[ing] uniform and consistent application of practices and procedures throughout the agency," *id.* at 7.1; it does not, however, address the prior-warning policy). Instead, the policy statements probably would be viewed by a court as informal guidelines for inspectors or other FDA employees. According to the FDA, formal "guidelines" state procedures or standards of general applicability that are not legal requirements but are acceptable to FDA for a subject matter which falls within the laws administered by the Commissioner." *Id.* at 10.90(b)(1). In this regard, "[t]he Commissioner advises that guidelines in staff manuals are not formal 'guidelines' unless there has been compliance with the requirements of [section 10.90.]" 42 Fed. Reg. 4694 (1977). It is not clear whether the guidelines discussed in this Article satisfy those requirements. *But see* I J. O'REILLY, *supra* note 12, § 4.07, at 4-35 (informal guidelines are contained, inter alia, in internal manuals that "are available to the public, 5 U.S.C. § 552(a)(2), but are not binding on the FDA"). The FDA and the United States Attorneys almost certainly will argue that the policy statements are internal policy statements that do not bind the FDA and do not create substantive rights in regulated parties. Support for this position is found in United States v. Caceres, 440 U.S. 741 (1979), Schweiker v. Hansen, 450 U.S. 785 (1981), and Brock v. Cathedral Bluffs Shale Oil Co., 796 F.2d 533 (D.C. Cir. 1986). *See* discussion *infra* at notes 107-16 and accompanying text.

23 FDA REGULATORY PROCEDURES MANUAL pt. 8-10-20, at 2. Note, however, that this provision also specifically states that "[s]ince FDA is under no legal obligation to warn firms or individuals that they or their products are in violation of the law before initiating formal regulatory action, responsible individuals should not assume that they will receive a Notice of Adverse Findings or Regulatory Letter before FDA initiated an administrative action or recommends an injunction, seizure, civil penalty and/or criminal proceeding." *Id.* pt. 8-10-20, at 1.

24 *Id.* pt. 8-30-30, at 2. A "Section 305 Notice" informs a company or individual that the FDA has discovered apparent violations of the Act. A "Section 305 Hearing" is then

. . . .

[In determining the need for a Section 305 citation], the [District Compliance Branch] reviewing officer should study the firm's regulatory history and determine who was responsible for violations and whether prior warning had been given.[25]

. . . .

In routine cases, it is incumbent upon the [field] office issuing the Section 305 Notice to assure that the firm and each individual to be cited has received prior warning, unless such warning is not required.[26]

. . . .

The question of citing individuals is a most important one which calls for careful consideration in every case. Bear in mind that prior warning is a prerequisite in all [cases] but [those involving] danger to health, fraud, and gross violations.[27]

. . . .

With the exception of cases involving gross violations, fraud, or danger to health, each prosecution must ordinarily contain counts which show a continuous course of conduct. This may consist of counts from two inspections, or counts from separate violative shipments at different points in time. This is because, except in aggravated circumstances, the agency ordinarily exercises its prosecutorial discretion to seek criminal sanctions against an individual only where a prior warning or other notification to the individual can be shown. The normal procedure of establishing a background of warning or other notification before prosecution will demonstrate to the U.S. Attorney, the judge, and the jury that there has been a continuous course of violative conduct and a failure to effect correction. Bear in mind that failure to correct a violative situation after notification will result in prosecution on the *first* incident as well as on subsequent incidents.[28]

. . . .

Except in cases of gross violations, fraud, or danger to health, prior warnings must ordinarily be shown for each individual charged, as discussed [above].[29]

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held to give that company or individual an opportunity to present their views before the FDA refers the case for criminal prosecution. *See Gel Spice Inc.*, 773 F.2d at 430. Again, the Section 305 notice and hearing are distinct from the FDA's prior-warning policy. *See supra* note 7.

25 FDA REGULATORY PROCEDURES MANUAL pt. 8-30-40, at 3.

26 *Id.* pt. 8-30-50, at 4.

27 *Id.* pt. 8-30-50, at 5.

28 *Id.* pt. 8-50-10, at 1-2 (emphasis in original).

29 *Id.* pt. 8-50-20, at 16 ("Format for Recommendation" of prosecution by District Compliance Branch). *See also* Fine, *The Philosophy of Enforcement*, 31 FOOD DRUG COSM. L.J. 324, 329 (1976) ("The law allows the FDA to charge individuals who have no knowledge of a violation, if they hold a responsible position and, by virtue of the position held, *should have known* of the violative condition. . . . We insist, however, that our prosecution recommendations include a factual record which demonstrates that every individual charged either knew or should have known of the violative conditions set forth, and was in a position to do something about those conditions but failed to do so." (emphasis in original)). Mr. Fine was the FDA's Associate Commissioner for Compliance when he wrote *The Philosophy of Enforcement*. *Id.* at 324.

Consistent with the FDA's prior-warning policy, a less-noted issue in *United States v. Park* was "the admissibility of evidence demonstrating that [Park, President of the corporation] was advised by the FDA in 1970 of insanitary conditions in [his company's] Philadelphia warehouse."[30] The Court upheld the admissibility of the evidence, stating that it "demonstrate[d] that [Park] was on notice that he could not rely on his system of delegation to subordinates . . . and that he must have been aware of the deficiencies of his system before the . . . violations were discovered."[31]

III. Legal Issues Raised by the FDA's Prior-Warning Policy

The involvement of administrative agencies in the criminal enforcement of federal statutes raises procedural and substantive legal issues rarely addressed by the parties in a given case or by the courts. The following discussion examines these issues. This Article suggests that the administrative law/criminal law overlap arising from such enforcement implicates substantial legal rights of potential defendants and that these rights should be vigorously protected by the courts. This protection is particularly crucial in the context of criminal enforcement of the Food, Drug and Cosmetic Act because that Act is essentially a strict liability statute.[32]

A. PROCEDURAL ISSUES: THRESHOLD REVIEWABILITY PROBLEMS

The question of reviewability is a threshold procedural issue for parties considering a challenge to a criminal prosecution initiated by the FDA. Although in-depth treatment is beyond the scope of this Article, the issue is important because pre-indictment review should not be relied upon automatically.

1. Pre-enforcement Judicial Review

Pre-enforcement/pre-indictment judicial review of a FDA decision to recommend criminal prosecution will rarely be available.[33]

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30 421 U.S. at 676.

31 *Id.* at 677-78. *See* Note, *Decisionmaking Models and the Control of Corporate Crime*, 85 YALE L.J. 1091, 1115-20 (1976)(discussing the FDA's prior warnings to Park and the significance of these warnings). *See also* United States v. Abbott Laboratories, 505 F.2d 565, 573 (4th Cir. 1974)(only those individuals who "share in the responsibility of distributing adulterated or misbranded drugs" are subject to criminal liability; " '[r]esponsibility' in turn depends upon knowledge, and if knowledge is established it depends further on the action or nonaction of the officer or employee after he has obtained knowledge"), *cert. denied*, 420 U.S. 990 (1975).

32 *See supra* note 10. *See also* Triangle Candy Co. v. United States, 144 F.2d 195, 199 (9th Cir. 1944).

33 The general question of judicial review of and deference to agency action has been

In *Ewing v. Mytinger & Casselberry, Inc.*,[34] the Supreme Court held that a district court "had no jurisdiction to review the [FDA's] determination of probable cause" to support a seizure of misbranded articles because the determination "in and of itself had no binding legal consequence."[35] The Court's reasoning fully applies to a pre-enforcement challenge to a FDA recommendation that a company or individual be prosecuted. The Court stated:

> Here an administrative agency is merely determining whether a judicial proceeding should be instituted. Moreover, its findings of probable cause, while a necessary prerequisite to multiple seizures, has no effect in and of itself. All proceedings for the enforcement of the Act or to restrain violations of it must be brought by and in the name of the United States . . . . Whether a suit will be instituted depends on the Attorney General, not on the administrative agency. He may or may not accept the agency's recommendation. If he does, seizures are made and libels are instituted. But the seizures and suits are dependent on the discretion of the Attorney General.[36]

A second relevant case in this regard is *Heckler v. Chaney*, in which the Supreme Court in 1985 held that "a decision of an administrative agency to exercise its 'discretion' not to undertake certain enforcement actions is [presumptively not] subject to judicial review under the Administrative Procedure Act."[37] In *Chaney*, several prison inmates sought relief from the FDA arguing that the use of

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addressed at length by the Supreme Court. *See, e.g.*, Young v. Community Nutrition Institute, 106 S. Ct. 2360, 2364-66 (1986)(upholding the FDA's interpretation of ambiguous statutory provisions); Chevron, U.S.A., Inc. v. Resources Defense Council, Inc., 467 U.S. 837, 842-44 (1984)(upholding the EPA's interpretation of statutory provision).

[34] 339 U.S. 594 (1950).

[35] *Id.* at 600.

[36] *Id.* at 598-99. *See also* National Milk Producers Federation v. Harris, 653 F.2d 339, 344 (8th Cir. 1981); Southeastern Minerals, Inc. v. Harris, 622 F.2d 758, 763-64 (5th Cir. 1980)("The district court acted in excess of its jurisdiction by enjoining the [FDA] from interfering with the manufacturing and marketing of appellee's premix product . . . . [T]he appellees . . . sought pre-enforcement review of the FDA's determination that probable cause existed to seize and to initiate enforcement proceedings against the . . . product, a review clearly proscribed by *Ewing*."); Parke-Davis & Co. v. Califano, 564 F.2d 1200, 1205 (6th Cir. 1977), *cert. denied*, 435 U.S. 942 (1978); 21 C.F.R. § 10.45(d)(2)(i) (1986)("[t]he [FDA] Commissioner shall object to judicial review . . . if . . . [a] matter is committed by law to the discretion of the Commissioner, e.g., a decision to recommend or not to recommend civil or criminal enforcement"). *Cf.* Gerator Corp. v. EEOC, 592 F.2d 765, 767-68 (4th Cir. 1979)(district court lacks jurisdiction to review the EEOC's "determination of reasonable cause on the charge of discrimination" because the determination "is merely preparatory to further proceedings" and "[n]o . . . finality exists").

[37] 470 U.S. at 823 (citation omitted). *See also* Schering Corp. v. Heckler, 779 F.2d 683 (D.C. Cir. 1985)(*Chaney* precludes judicial review of a settlement agreement under which the FDA agreed not to pursue enforcement actions against a company). The Supreme Court made clear in *Chaney* that its holding was limited to judicial review under the APA. 470 U.S. at 837-38. Therefore, *Chaney* does not preclude review of a FDA

drug injections to carry out death penalties violated the Food, Drug and Cosmetic Act. The inmates petitioned the FDA to "take various investigatory and enforcement actions to prevent these perceived violations [including] recommend[ing] the prosecution of all those in the chain of distribution who knowingly distribute or purchase drugs with intent to use them for human execution."[38] When the FDA refused to act, the inmates relied upon the APA to seek judicial review of the agency's refusal to initiate any such enforcement actions.

By holding that a FDA decision "*not to exercise* its enforcement authority"[39] is "not subject to review under the APA,"[40] the Court distinguished such non-action from those instances in which "an agency *does* act to enforce."[41] This language arguably supports the conclusion that a FDA criminal referral *is* subject to judicial review.[42] The overall tenor of the Court's decision is to the contrary, however, and, in support, the Court specifically cited the FDA regulation which states that the Agency " 'shall object to judicial review . . . if . . . [t]he matter is committed by the law to the discretion of the Commissioner, e.g., a decision to recommend or not to recommend civil or criminal enforcement action . . . .' "[43] Thus, although *Chaney* is relevant to this discussion, its import remains unclear.

In light of *Ewing* and *Chaney*, a party has little chance of successfully challenging at the pre-indictment stage a decision by the FDA to refer a case for criminal prosecution.[44] The FDA is required by its regulations to oppose such judicial review,[45] and the precedents indicate that the courts would most likely uphold the FDA's

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enforcement action or inaction that is alleged to be unconstitutional. *See generally* Sunstein, *Reviewing Agency Inaction After* Heckler v. Chaney, 52 U. CHI. L. REV. 653 (1985).

38 *Chaney*, 470 U.S. at 824.

39 *Id.* at 828 (emphasis in original).

40 *Id.* at 838.

41 *Id.* at 832 (emphasis in original).

42 *See* Heterochemical Corp. v. FDA, 644 F. Supp. 271 (E.D.N.Y. 1986)(applying this distinction in a non-criminal action to reject the FDA's argument of non-reviewability)(emphasis added).

43 *Chaney*, 470 U.S. at 836 (citing 21 C.F.R. § 10.45(d)(2) (1984)).

44 Cases that have allowed pre-enforcement review of FDA actions are easily distinguished from the case in which a single individual or company has allegedly violated the Act's provisions. *See, e.g.*, Abbott Laboratories v. Gardner, 387 U.S. 136 (1967)(pre-enforcement review of an industry-wide FDA labeling regulation). In *Abbott*, the Court specifically distinguished *Ewing* as a "proceeding against a particular drug manufacturer," rather than an agency "promulgation of a self- operative industry-wide regulation." *Id.* at 137. The Court added that the *Ewing* decision "was quite clearly correct" and that, "like a determination by a grand jury that there is probable cause to proceed against an accused, [the FDA's probable cause] finding . . . only has vitality once a proceeding is commenced, at which time appropriate challenges can be made." *Id.* at 147.

45 21 C.F.R. 10.45(d)(2).

position.[46]

2. *Post-enforcement Judicial Review*

There are two post-enforcement/post-indictment reviewability dilemmas. Unlike the pre-enforcement problem, these issues do not involve the actual unavailability of judicial review. Instead, they involve the problem of extreme judicial deference that, in effect, ordinarily results in a total lack of judicial review. Two problems arise because this deference operates at two levels: (1) the FDA may decide to pursue criminal prosecution, rather than pursuing alternative sanctions, and (2) the executive branch—initially the FDA and subsequently the United States Attorney—may decide to prosecute.

In *Butz v. Glover Livestock Commission Co.*,[47] the Supreme Court reaffirmed the proposition that an agency's choice of sanctions may not be overturned unless it is "unwarranted in law or . . . without justification in fact . . . ."[48] The Court rejected the argument that an administrative sanction is "rendered invalid in a particular case because it is more severe than sanctions imposed in other cases."[49] The Court's reasoning in this regard could be used to refute an argument that a decision to recommend prosecution in the face of non-prosecution of similarly situated persons is arbitrary and capricious.[50] The Court stated:

> We read the Court of Appeals' opinion to suggest that the sanction was "unwarranted in law" because "uniformity of sanctions for similar violations" is somehow mandated by the [Packers and Stockyards] Act. We search in vain for that requirement in the statute. . . . [M]ere unevenness in the application of the sanction does not render its application in a particular case "unwarranted in law."[51]

In light of *Butz*, therefore, it is safe to conclude that the choice of prosecution as the appropriate sanction, if it is reviewable at all, is subject to extreme judicial deference.[52] Furthermore, "mere un-

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46 Moreover, even if judicial review were afforded, courts would almost always defer to the FDA's decision. "As long as the agency is choosing how to allocate finite enforcement resources, the agency's choice will be entitled to substantial deference, for the choice among valid alternative enforcement policies is precisely the sort of choice over which agencies generally have been left substantial discretion by their enabling statutes." *Chaney*, 470 U.S. at 842 (Marshall, J., concurring).

47 411 U.S. 182 (1973).

48 *Id.* at 185-86 (quoting American Power & Light Co. v. SEC, 329 U.S. 90, 112-13 (1946)).

49 *Id.* at 187.

50 *See infra* notes 72-79 and accompanying text.

51 *Butz*, 411 U.S. at 186, 188.

52 *See, e.g.*, American Power & Light Co. v. SEC, 329 U.S. 90, 112-13 (1946); Wayne Cusimano, Inc. v. Block, 692 F.2d 1025, 1030 (5th Cir. 1982); Niagara Mohawk Power Corp. v. FPC, 379 F.2d 153, 159 (D.C. Cir. 1967)("The breadth of agency discretion is,

evenness in the application of th[at] sanction," if it exists, does not render the sanction's application to a company or individual unwarranted in law.[53]

A second post-enforcement reviewability problem involves the extreme judicial deference afforded a decision by the executive branch to prosecute. "Our legal system has traditionally accorded wide discretion to criminal prosecutors in the enforcement process, and similar considerations have been found applicable to administrative prosecutors as well."[54] Only in cases involving egregious conduct or constitutional violations[55] will courts disturb a prosecutor's exercise of discretion.[56] If a party challenges a decision by the

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if anything, at [a] zenith when the action assailed relates primarily not to the issue of ascertaining whether conduct violates the statute . . . but rather to the fashioning of policies, remedies and sanctions.").

[53] *Butz*, 411 U.S. at 188. *See, e.g.*, Moog Industries, Inc. v. FTC, 355 U.S. 411 (1958)(FTC's decision to order one company to cease and desist from certain practices without likewise requiring other companies engaged in the same practices to do so could not be overturned "in the absence of a patent abuse of discretion"); Villela v. Dep't of the Air Force, 727 F.2d 1574, 1576-77 (Fed. Cir. 1984)("[t]he choice of penalty is generally left to agency discretion. . . . That Villela was removed [from the Air Force] and [two others who also went AWOL] were reprimanded provides no basis for reversal. An agency need not exercise its discretion identically in every case"); Sartain v. SEC, 601 F.2d 1366, 1375 (9th Cir. 1979)(imposition of sanction "not rendered invalid in particular case because it is more severe than sanctions imposed in other cases").

[54] Marshall v. Jerrico, Inc., 446 U.S. 238, 248 (1980)(citations omitted). *See also* United States v. Batchelder, 442 U.S. 114, 124 (1979)("[w]hether to prosecute and what charge to file . . . are decisions that generally rest in the prosecutor's discretion"). *See generally* K. DAVIS, ADMINISTRATIVE LAW TREATISE ch. 9 (2d ed. 1979 & 1982 Supp.); Vorenberg, *Decent Restraint of Prosecutorial Power*, 94 HARV. L. REV. 1521 (1981).

[55] *See, e.g.*, Bordenkircher v. Hayes, 434 U.S. 357, 365 (1978)("broad though [a prosecuting attorney's] discretion may be, there are undoubtedly constitutional limits upon its exercise"); Ganger v. Peyton, 379 F.2d 709, 714 (4th Cir. 1967); United States v. Velsicol Chemical Corp., 498 F. Supp. 1255, 1256-57 (D.D.C. 1980)(dismissing an indictment on due process grounds because of "prosecutorial vindictiveness" where the prosecutor acted upon his threat to increase the charges against a corporation and various individuals to include a charge of conspiring to defraud the FDA if they plead nolo contendere to misdemeanor FDA adulteration charges).

[56] Indeed, many courts have held that the decision whether to prosecute is wholly unreviewable in part because of the separation of powers doctrine. *E.g.*, United States v. Kysar, 459 F.2d 422, 424 (10th Cir. 1972)(the United States Attorney "has the power to prosecute or not to prosecute; this decision is not reviewable by any court"); Newman v. United States, 382 F.2d 479 (D.C. Cir. 1967)("United States Attorney consent to guilty plea tendered by codefendant, for lesser offense, while refusing to grant same plea for the defendant was not constitutional violation"); United States v. Cox, 342 F.2d 167, 171 (5th Cir.)("as an incident of the constitutional separation of powers . . . the courts are not to interfere with the free exercise of the discretionary powers of the attorneys of the United States and their control over criminal prosecutions"), *cert. denied*, 381 U.S. 935 (1965); Anderson v. Norfolk & Western Ry., 349 F. Supp. 121, 122 (W.D. Va. 1972)("within United States Attorney's discretion to prosecute possible statutory violations"). *See also* United States v. Nixon, 418 U.S. 683, 693 (1974)("the Executive Branch has exclusive and absolute discretion to decide whether to prosecute a case")(dictum).

United States Attorney to prosecute, that party will have to overcome the formidable body of precedent that largely shields such decisions from judicial review.[57]

Similarly, a challenge to the FDA's decision to recommend prosecution, if it is reviewable at all, would encounter the many cases that give extreme deference to the prosecutorial decisions of administrative agencies. In *Pseudonym Taxpayer v. Miller*, for example, the district court held that it did not have jurisdiction to restrain the IRS from recommending to the United States Attorney that a taxpayer be criminally prosecuted:

> [I]t is not a judicial function to poke about in the discretionary operations of an agency in the Executive Branch .... There are well-established statutes and regulations, and no indication that any constitutional or statutory right is being invoked. I.R.S. has primary jurisdiction to decide whether to recommend and whether to refer for prosecution. This is strictly a discretionary Executive Branch function in which the judiciary should not interfere.[58]

This reasoning applies equally to a prosecution recommendation by the FDA.

Recent cases, however, suggest a shift in this view. *See Chaney*, 470 U.S. at 838-39 (Brennan, J., concurring); *id.* at 845-50 (Marshall, J., concurring); K. DAVIS, *supra* note 54, § 9.6, at 239-40 ("The key to understanding the law of reviewability of enforcement discretion does not lie in . . . reconcil[ing] the irreconcilable cases [but] . . . in recognizing that the law has been in transition and that case law since 1974 is strongly on the side of reviewability.").

[57] *See* cases cited *supra* note 56. *See also* United States v. DeBright, 730 F.2d 1255, 1257 (9th Cir. 1984); United States v. Spence, 719 F.2d 358, 361 (11th Cir. 1983)(per curiam); United States v. Lau Tung Lam, 714 F.2d 209, 210 (2d Cir.), *cert. denied*, 464 U.S. 942 (1983); Gray v. Bell, 712 F.2d 490, 514 (D.C. Cir. 1983), *cert. denied*, 465 U.S. 1100 (1984); United States v. Valle, 697 F.2d 152, 154 (6th Cir.), *cert. denied*, 461 U.S. 918 (1983).

[58] Pseudonym Taxpayer v. Miller, 497 F. Supp. 78, 81 (D.N.J. 1980). *See supra* note 46. *See also* Groder v. United States, No. 86-2054, slip op. at 8 (4th Cir. April 9, 1987)("We emphasize at the outset that the individual revenue agent and his supervisor enjoy latitude in making the difficult [criminal] referral decision. They also deserve deference from a reviewing court."); Brock v. Cathedral Bluffs Shale Oil Co., 796 F.2d 533, 538 (D.C. Cir. 1986)("an agency's exercise of its enforcement discretion [is] an area in which the courts have traditionally been most reluctant to interfere"); Presinzano v. Hoffman-La Roche, Inc., 726 F.2d 105, 110 (3d Cir. 1984); *National Milk Producers Federation*, 653 F.2d at 343, 344 n.11 ("[t]he executive branch and its departments enjoy a discretion in the initiation of investigative, enforcement, and prosecutorial actions limited only by constitutional strictures and relevant statutory directives"); Gordon v. Heimann, 514 F. Supp. 659, 662 (N.D. Ga. 1980)("[t]he decision by the Comptroller [of the Currency] to investigate or bring criminal charges in a specific case is an enforcement decision not reviewable by the court").

B. SUBSTANTIVE ISSUES: CONSTITUTIONAL RIGHTS, THE REQUIREMENT OF CONSISTENT AGENCY TREATMENT AND THE *ACCARDI* DOCTRINE

Assuming that a party can overcome the considerable hurdle posed by reviewability problems, the question arises whether substantive legal rights are implicated by the involvement of administrative agencies in the criminal enforcement of federal laws. This Article suggests that such rights are, in fact, implicated.

1. Constitutional Rights

An argument can be made that prosecution under the hypothetical situation used in this Article[59] would violate constitutional due process and equal protection rights because United States Attorneys ordinarily have not prosecuted similarly situated persons. The Supreme Court provided support for such an argument in the 1886 case of *Yick Wo v. Hopkins*.[60] In *Yick Wo*, the Court reversed the conviction of a Chinese man accused of operating a laundry in violation of a county ordinance because the local sheriff enforced the ordinance in an unconstitutional manner by discriminating against persons of Chinese descent. The Court reasoned:

> Though the law itself be fair on its face and impartial in appearance, yet, if it is applied and administered by public authority with an evil eye and an unequal hand, so as practically to make unjust and illegal discriminations between persons in similar circumstances, material to their rights, the denial of equal justice is still within the prohibition of the Constitution.[61]

The Court reaffirmed this broad proposition in the 1979 case of *United States v. Batchelder*, stating that "[s]electivity in the enforcement of criminal laws . . . is subject to constitutional constraints."[62]

This argument, though available, is not likely to succeed.[63]

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59 *See supra* notes 5-6 and accompanying text.

60 Yick Wo v. Hopkins, 118 U.S. 356 (1886).

61 *Id.* at 373-74.

62 *Batchelder*, 442 U.S. at 125 (holding that a prosecutor's selection of one statutory penalty provision rather than another did not, under the facts of the case, violate constitutional constraints). *See also Chaney*, 470 U.S. at 838; Britton v. Rogers, 631 F.2d 572, 577 (8th Cir. 1980)("[t]he equal protection clause is applicable not only to discriminatory legislative action, but also to governmental action in the administration and enforcement of law"), *cert. denied*, 451 U.S. 939 (1981); United States v. Johnson, 577 F.2d 1304, 1307 (5th Cir. 1978); United States v. McDonald, 553 F. Supp. 1003, 1006 (S.D. Tex. 1983). *See generally* Annotation, *What Constitutes Such Discriminatory Prosecution or Enforcement of Laws as to Provide a Valid Defense in Federal Criminal Proceedings*, 45 A.L.R. FED. 732 (1979).

63 *See generally* Note, *The Procedural Due Process Approach to Administrative Discretion: The Courts' Inverted Analysis*, 95 YALE L.J. 1017 (1986). The constitutional arguments address actions of the United States Attorney, rather than of the FDA. It is questionable

Very few cases fall within the limited class of cases in which constitutional deprivations are likely to be found.[64] The Supreme Court has stated that "the conscious exercise of some selectivity in enforcement is not in itself a federal constitutional violation."[65] To support a due process or equal protection challenge to selective prosecution, a party must show that the prosecution either "was deliberately based upon an unjustifiable standard such as race, religion, or other arbitrary classification,"[66] or that it resulted from "the defendant's exercise of a protected right."[67] Moreover, the challenging party must "overcome the presumption that the prosecution was undertaken in good faith and in a nondiscriminatory manner."[68]

In *United States v. Berrios*, which is the most frequently cited case in this area, the Second Circuit summarized the defendant's "heavy burden" as follows:

To support a defense of selective or discriminatory prosecution, a de-

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whether, in and of themselves, the FDA's actions fall within the coverage of the due process clause. In Hannah v. Larche, 363 U.S. 420 (1960), the Supreme Court refused to extend the full panoply of due process protections to proceedings before the Commission on Civil Rights, a "purely investigative agenc[y]" that the Court compared to the FDA. *Id.* at 442, 444, 470 app. The Court's reasoning in *Hannah* could be applied to a FDA recommendation to prosecute. The Court stated:

> [T]he Commission['s] . . . function is purely investigative and fact-finding. It does not adjudicate. It does not . . . indict, punish, or impose any legal sanctions. It does not make determinations depriving anyone of his life, liberty, or property. In short, [it] does not and cannot take any affirmative action which will affect an individual's legal rights. The only purpose of its existence is to find facts which may subsequently be used as a basis for legislative or executive action [including the possibility of criminal prosecutions.]

Id. at 441. *See also Ewing*, 339 U.S. at 598 (claimant's opportunity to challenge the FDA's probable cause determination in the subsequent libel action for seizure "satisfies the requirements of due process"); *Georator Corp.*, 592 F.2d at 768 ("[w]hen only investigative powers of an agency are utilized, due process considerations do not attach").

64 *See, e.g.*, United States v. Fletcher, 344 F. Supp. 332 (E.D. Va. 1972). In *Fletcher*, the defendant argued that he had been "denied equal protection . . . because other [air force] members . . . who are taken into custody for [DWI] are carried before their Commanding Officer rather than charged under the statute." *Id.* at 338. The court held that "[t]he mere fact that the police . . . did not follow the statute in other cases would not entitle defendant to relief. . . . The police do not arrest all violators of the law, but the fact that one escapes arrest does not entitle one properly arrested to be released." *Id.*

65 Oyler v. Boles, 368 U.S. 448, 456 (1962)(failure to prosecute others as habitual offenders did not deprive petitioner, convicted as a habitual offender, of equal protection).

66 *Id.*

67 United States v. Duncan, 598 F.2d 839, 869 (4th Cir.)(rejecting petitioner's selective prosecution argument), *cert. denied*, 444 U.S. 871 (1979).

68 United States v. Christopher, 700 F.2d 1253, 1258 (9th Cir.)(rejecting selective prosecution argument of protestors who were convicted of the misdemeanor offense of being present on federal property after normal working hours), *cert. denied*, 461 U.S. 960 (1983). *Accord* United States v. Niemiec, 611 F.2d 1207, 1209 (7th Cir. 1980); United States v. Lichenstein, 610 F.2d 1272, 1281 (5th Cir.), *cert. denied*, 447 U.S. 907 (1980).

> fendant bears the heavy burden of establishing, at least *prima facie*, (1) that, while others similarly situated have not generally been proceeded against because of conduct of the type forming the basis of the charge against him, he has been singled out for prosecution, and (2) that the government's discriminatory selection of him for prosecution has been invidious or in bad faith, i.e., based upon such impermissible considerations as race, religion, or the desire to prevent his exercise of constitutional rights.[69]

By applying the *Berrios* test or a variation thereof, it is apparent that the vast majority of cases have rejected the equal protection or due process arguments which are based upon allegations of selective prosecution.[70]

A heavy burden is also likely if the constitutional argument is couched in terms of discriminatory enforcement. A defendant would first have to show that similarly situated persons have not been prosecuted. Because FDA prosecutions are heavily fact-specific, it may be difficult to show that similarly situated persons have not been prosecuted. The greater obstacle, however, is showing that the decision to prosecute was based upon unjustifiable standards such as race, religion or the exercising of federal constitutional rights.[71] It will be virtually impossible to satisfy this second essential element of the discriminatory enforcement defense in the context of a FDA criminal prosecution.

2. *The Right To Consistent And Evenhanded Agency Treatment*

If the FDA has not recommended prosecution of persons similarly situated to a particular individual or corporation being prosecuted, the prosecution recommendation could be classified as arbitrary, capricious, and an abuse of agency discretion.[72] It is

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69 United States v. Berrios, 501 F.2d 1207, 1211 (2d Cir. 1974).

70 *See, e.g.*, United States v. Hoover, 727 F.2d 387 (5th Cir. 1984)(rejecting air traffic controller's discriminatory prosecution argument); United States v. Salazar, 720 F.2d 1482, 1487 (10th Cir. 1983)(rejecting food stamp recipient's selective prosecution argument), *cert. denied*, 469 U.S. 1110 (1985); United States v. Bell, 506 F.2d 207, 221-22 (D.C. Cir. 1974)(rejecting drug offender's selective enforcement argument). *Cf.* LeClair v. Saunders, 627 F.2d 606, 608 (2d Cir. 1980)(rejecting a dairy farmer's equal protection challenge to a state's selective enforcement of a civil regulation), *cert. denied*, 450 U.S. 959 (1981); Cook v. City of Price, Carbon County, Utah, 566 F.2d 699, 701 (10th Cir. 1977)(rejecting an equal protection challenge to a city's selective enforcement of a civil zoning regulation).

71 *See* United States v. Crowthers, 456 F.2d 1074 (4th Cir. 1972)(reversing convictions that were based upon discriminatory prosecutions of persons exercising their first amendment rights); Tolbert v. City of Memphis, Tennessee, 568 F. Supp. 1285 (W.D. Tenn. 1983)(enjoining city from enforcing an ordinance against a topless bar because the city enforced the ordinance in a discriminatory manner that chilled first amendment rights).

72 Again, however, the problem of reviewability must be kept in mind. *See supra* notes

firmly established that an agency's unjustified discriminatory treatment of similarly situated parties constitutes arbitrary and capricious agency action.[73] This rule has been applied to the FDA in civil actions.[74] Although there are no criminal cases in which the rule has been applied or discussed, it has been relied upon with regard

33-58 and accompanying text. The APA provides that "[a] person suffering legal wrong because of agency action . . . is entitled to judicial review thereof." 5 U.S.C. 702 (Supp. III 1985). However, judicial review is available only for "final agency action," 5 U.S.C. § 704 (1982) and is unavailable for "agency action [that] is committed to agency discretion by law," *id.* § 701(a)(2). The FDA and the United States Attorney would most likely argue that a FDA decision to recommend prosecution cannot be reviewed under the APA because (a) such a decision does not represent final agency action, or (b) such a decision is committed by law to agency discretion. *See* 21 C.F.R. § 10.45(d)(2)(i) (1986)("[t]he [FDA] Commissioner shall object to judicial review of a matter if . . . [it] is committed by law to the discretion of the Commissioner, e.g., a decision to recommend or not to recommend civil or criminal enforcement action"). *See also Chaney*, 470 U.S. at 837; United States v. J. Treffiletti & Sons, 496 F. Supp. 53, 56 (N.D.N.Y. 1980)(refusing to dismiss the misdemeanor indictments of individuals named as defendants for violations of the Food, Drug, and Cosmetic Act, rejecting, inter alia, an unspecified APA argument, and holding without legal citation that "[t]he [APA] does not apply in this criminal prosecution based upon the return of an indictment by the Grand Jury"). *Cf. Gordan*, 514 F. Supp. at 662 (decision by Comptroller of the Currency as to whether to bring criminal charges is not subject to APA review because the APA "does not authorize review of decisions committed by law to agency discretion").

[73] *See, e.g.*, Northern Natural Gas Co. v. FERC, 785 F.2d 338, 343 (D.C. Cir. 1986); Green County Mobilephone v. FCC, 765 F.2d 235, 237 (D.C. Cir. 1985)("[w]e reverse the Commission not because the strict rule it applied is inherently invalid, but rather because the Commission has invoked the rule inconsistently. We find that the Commissioner has not treated similar cases similarly"); McHenry v. Bond, 668 F.2d 1185, 1192-93 (11th Cir. 1982); Crestline Memorial Hosp. Ass'n v. NLRB, 668 F.2d 243, 245 (6th Cir. 1982)(NLRB cannot "treat similar situations in dissimilar ways"(quoting Burinskas v. NLRB, 357 F.2d 822, 827 (D.C. Cir. (1966))); Helton v. NLRB, 656 F.2d 883, 891 n.43 (D.C. Cir. 1981); United Gas Pipeline Co. v. FERC, 649 F.2d 1110, 1115 (5th Cir. 1981); Ace Motor Freight, Inc. v. ICC, 557 F.2d 859, 862 (D.C. Cir. 1977); Oil, Chem. & Atomic Workers Int'l Union, AFL-CIO v. NLRB, 547 F.2d 598, 603 n.4 (D.C. Cir. 1976), *cert. denied*, 429 U.S. 1078 (1977); Contractors Transport Corp. v. United States, 537 F.2d 1160, 1162 (4th Cir. 1976)("[p]atently inconsistent application of agency standards to similar situations lacks rationality" and is prohibited under the APA's arbitrary and capricious standard); Brennan v. Gilles & Cotting, Inc., 504 F.2d 1255, 1264 (4th Cir. 1974); Sirbo Holdings, Inc. v. Commissioner, 476 F.2d 981, 987 (2d Cir. 1973); Hill v. FPC, 335 F.2d 355, 363 (5th Cir. 1964); Keen Transport, Inc. v. United States, 446 F. Supp. 5, 9 (N.D. Ohio 1976); Nat'l Alliance of Postal & Federal Employees v. Nickerson, 424 F. Supp. 323, 327 (D.D.C. 1976); Interstate Contract Carrier Corp. v. United States, 389 F. Supp. 1159, 1163 (D. Utah 1974). *See also* Note, *Judicial Review of Reversals of Policy by Administrative Agencies*, 68 HARV. L. REV. 1251 (1955).

[74] *E.g.*, United States v. Diapulse Corp. of America, 748 F.2d 56, 62 (2d Cir. 1984)("[w]e must insist that the FDA apply its scientific conclusions evenhandedly and that it not 'grant to one person the right to do that which it denies to another similarly situated.' So long as the FDA allows [one manufacturer to market electric devices without prior FDA approval], we have no choice but to allow [petitioner] also [to do so]. Deference to administrative discretion or expertise is not a license to a regulatory agency to treat like cases differently.")(citation omitted).

to agency sanctions.[75] Moreover, the essence of the rule—equality of treatment—has been specifically endorsed by both the FDA[76] and the Department of Justice as a desirable enforcement goal.[77]

This administrative law principle is grounded in the unassailable proposition that agencies must not discriminate against similarly situated parties, and it recognizes that "[a] fundamental of justice is equality of treatment."[78] It is an eminently reasonable principle, and a party who relies upon it is not required to overcome the overwhelming contrary precedent that confronts a constitutional challenge to discriminatory enforcement.[79]

3. The Accardi *Doctrine And The Right To Insist Upon Agency Compliance With Its Own Rules*

The criminal prosecution of an individual who has not first

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[75] *Compare* Arthur Lipper Corp. v. SEC, 547 F.2d 171, 184 (2d Cir. 1976)(modifying the sanctions imposed on a broker-dealer because of "the tremendous disparity between the sanctions invoked . . . and that imposed on two other brokers whose violations were perhaps more clear"), *cert. denied*, 434 U.S. 1009 (1978), *with* General Securities Corp. v. SEC, 583 F.2d 1108, 1110 (9th Cir. 1978)(per curiam)(refusing to modify the sanctions imposed on a broker-dealer and rejecting the argument that "the sanctions [were] out of line with those imposed in [similar] cases;" the court held that "a sanction . . . is not rendered invalid because it varies from that applied in other cases" and that, in any event, the petitioner's situation was "readily distinguishable" from the other cases upon which he relied).

[76] *See* 21 C.F.R. § 7.1 (1986)("[t]his part [Enforcement Policy] is promulgated to . . . assure uniform and consistent application of practices and procedures throughout the agency").

[77] U.S. DEP'T OF JUSTICE, PRINCIPLES OF FEDERAL PROSECUTION i (1980)(these Principles are intended to "promote the reasoned exercise of prosecutorial authority, and contribute to the fair, evenhanded administration of the federal criminal laws"); U.S. DEP'T OF JUSTICE, UNITED STATES ATTORNEYS' MANUAL § 7-5.126 (1981)("[a]n affirmative obligation to coordinate all [criminal FDA] actions exists among the [FDA], the United States Attorney and the Consumer Affairs Section in order to facilitate consistent treatment of cases across the country").

[78] Jones v. Califano, 576 F.2d 12, 20 (2d Cir. 1978).

[79] *See supra* note 73. *See also* Marriott In-Flite Services Division of Marriott Corp. v. NLRB, 417 F.2d 563, 565 (5th Cir. 1969)("[t]he Board . . . allowed employees certain rights in one geographic area, and different, more extensive rights in all other geographic areas without offering any justification for the disparate treatment. . . . If the agency establishes a general policy then departs from it, judicial approval of the departure will be withheld in the absence of an explanation"), *cert. denied*, 397 U.S. 920 (1970); Mary Carter Paint Co. v. FTC, 333 F.2d 654, 660 (5th Cir. 1964)(Brown, J., concurring)(refusing to enforce an FTC cease and desist order because of the FTC's departure from earlier pronouncements on the legality of the challenged advertising practice, "[the] law does not permit an agency to grant to one person the right to do that which it denies to another similarly situated. There may not be a rule for Monday, another for Tuesday, a rule for general application, but denied outright in a specific case"), *rev'd on other grounds*, 382 U.S. 46 (1965). *But see* Barnum v. Nat'l Transp. Safety Board, 595 F.2d 869, 871 (D.C. Cir. 1979)(rejecting petitioner's argument that his 150-day suspension was "not in accord with Board policy and precedent").

been given notice and an opportunity to remedy an alleged FDA violation would appear to be a violation of the *Accardi* doctrine. This doctrine was summarized in a recent district court decision:

> [W]hen the rights of an individual are affected, an agency must follow its own procedure, even where the intended procedures are more rigorous than otherwise would be required. Should an agency in its proceedings violate its rules and prejudice results, the proceedings are tainted and any action resulting from the proceedings cannot stand.[80]

In *Accardi v. Shaughnessy,* the Court reversed a discretionary decision by the Board of Immigration Appeals ("the Board") to deny a petitioner's application for suspension of deportation because the Board failed to follow its procedural regulations for "processing [such] an . . . application."[81] The Board was appointed by the Attorney General and was subject to his overview, but the relevant regulations specifically required the Board "to exercise its own judgment when considering appeals."[82] The Board failed to do so with petitioner's appeal because the Attorney General had, in effect, dictated the Board's decision. Under the regulations, the Attorney General was not supposed to act unless certain things happened first, including the exercise of independent judgment by the Board. Although such predicate acts did not occur, the Attorney General acted anyway, contrary to the regulations. This action would be analogous to either the FDA recommending prosecution of an individual in a routine case or the United States Attorney prosecuting that individual even though the prefatory requirements established by the FDA's prior-warning policy had not been met. To this extent, and to the extent that the challenged agency action was discretionary, *Accardi* provides direct support for the conclusion that the FDA cannot recommend prosecution of an individual who has not been given a prior warning in compliance with the FDA's policy.

The doctrine which resulted from the *Accardi* decision is based upon both administrative law and due process principles, although its precise legal foundation is unclear.[83] The doctrine has basically

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[80] Borowski v. Heckler, 581 F. Supp. 549, 552 (N.D. Ind. 1984)(citation omitted). *See also* VanderMolen v. Stetson, 571 F.2d 617, 624 (D.C. Cir. 1977)("It is . . . a fundamental tenet of our legal system that the Government must follow its own regulations. Actions by an agency of the executive branch in violation of its own regulations are illegal and void.").

[81] 347 U.S. 260, 265 (1954). Earlier decisions of the Court also support the *Accardi* doctrine. *See, e.g.*, Bridges v. Wixon, 326 U.S. 135, 153 (1945)("The rules afford protection at th[e] crucial stage of the proceedings or not at all. . . . '[O]ne under investigation with a view to deportation is legally entitled to insist upon the observance of rules promulgated by the Secretary pursuant to law' "(citation omitted)).

[82] *Accardi*, 347 U.S. at 266.

[83] *Compare* Board of Curators of the University of Missouri v. Horowitz, 435 U.S. 78,

three essential elements. First, there must be an agency rule, regulation, policy or procedure that governs a particular subject. It does not apply to isolated, ad hoc or informal agency positions on such a subject.[84] Second, the rule, regulation, policy or procedure must actually affect the rights of individuals, rather than being "a mere housekeeping provision."[85] Third, an individual must be prejudiced because of an agency's failure to follow the rule, regulation, policy or procedure.[86] The FDA, like other federal agencies, is

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92 n.8 (1978)(dictum)(*Accardi* "enunciate[s] principles of federal administrative law rather than of constitutional law binding upon the States") *and* Vitarelli v. Seaton, 359 U.S. 535, 547 (1959)(Frankfurter, J., concurring)(*Accardi* doctrine is a "judicially evolved rule of administrative law") *with* United States v. Caceres, 440 U.S. 741, 754 (1979)("[a]gency violations of their own regulations, whether or not also in violation of the Constitution, may well be inconsistent with the standards of agency action which the APA directs the courts to enforce") *and id.* at 758 n.1 (Marshall, J., dissenting)("Although not always predicated on the Due Process Clause, [the *Accardi* doctrine is] explicable in no other terms . . . . [It] cannot be dismissed as federal administrative law"). *See also* Simmons v. Block, 782 F.2d 1545, 1549-50 (11th Cir. 1986)(*Accardi* doctrine applied as a rule of administrative law); Jones v. Board of Governors of the University of North Carolina, 704 F.2d 713, 717 (4th Cir. 1983)("significant departures from stated procedures of government . . . if sufficiently unfair and prejudicial, constitute procedural due process violations"); United States v. Heffner, 420 F.2d 809, 812 (4th Cir. 1969)(*Accardi* decision based upon "a violation of due process"); Doe v. General Services Admin., 544 F. Supp. 530, 537, 542 (D. Md. 1982)(*Accardi* doctrine described in the court's opinion as a "principle[] of administrative law," but in the court's resulting order as a matter of "due process rights under the Fifth Amendment").

84 *Cf.* Edison Pharmaceutical Co. v. FDA, 600 F.2d 831, 843 (D.C. Cir. 1979)(rejecting manufacturer's argument that "allegedly different treatment rendered by the FDA to [a different] drug" required the FDA to treat the manufacturer's drug in the similar manner).

85 United States v. Howard, 590 F.2d 564 (4th Cir.), *cert. denied*, 440 U.S. 976 (1979). In *Howard*, the Fourth Circuit rejected the argument that petitioner's conviction should be reversed because the government failed to follow "the dual prosecution guidelines formulated by the Department of Justice" for dealing with federal cases that have already been subjected to state prosecution (the so-called "*Petite*" policy). *Id.* at 567. The court held that the *Petite* policy is "a mere housekeeping provision" and held it inapplicable to a case in which the government failed to comply with a "regulation having force of law" and affecting individual rights. *Id.* at 567-68 (citation omitted). *Accord* United States v. Snell, 592 F.2d 1083, 1087 (9th Cir.)("a violation of the internal housekeeping rules of the Department of Justice doe not entitle Snell to dismissal of the indictment"), *cert. denied*, 442 U.S. 944 (1979); United States v. Hayes, 589 F.2d 811, 818 (5th Cir.), *cert. denied*, 444 U.S. 847 (1979). *See generally* Annotation, *Effect on Federal Criminal Prosecution or Conviction of Prosecutor's Noncompliance with Petite Policy: Requiring Prior Authorization of Attorney General for Federal Trial Where Accused Has Been Previously Prosecuted for Same Acts in State Court*, 51 A.L.R. FED. 852 (1981).

86 *See supra* note 15. *See generally* Raven-Hansen, *Regulatory Estoppel: When Agencies Break Their Own "Laws,"* 64 TEX. L. REV. 1 (1985); Smolla, *The Erosion of the Principle that the Government Must Follow Self-Imposed Rules*, 52 FORDHAM L. REV. 472 (1984); Note, *Violations by Agencies of Their Own Regulations*, 87 HARV. L. REV. 629 (1974). Clearly, there is a relationship between the requirements of the *Accardi* doctrine and the requirement that agencies treat similarly situated parties in a consistent manner. The relationship arises

subject to the doctrine's requirements.[87]

The argument advanced here is that, contrary to the *Accardi* doctrine, a FDA recommendation of prosecution would constitute a violation of the agency's stated policy of not prosecuting individuals in routine cases if the individuals have not had prior warning of the violations and an opportunity to remedy them.[88] Such an argument is supported by the numerous cases in which the *Accardi* doctrine has been applied to invalidate agency actions.[89]

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when the dissimilar treatment results from the agency's departure from an express rule or policy.

87 *E.g.*, Southeastern Minerals, Inc. v. Harris, 622 F.2d 758, 766 (5th Cir. 1980)("the statement of policy [in the FDA's Compliance Policy Guide] represents the FDA's formal position . . . and obligates the agency to act in a manner consistent with that policy until it is amended or revoked"); *Heterochemical Corp.*, 644 F. Supp. at 276. *Cf. Triangle Candy Co.*, 144 F.2d at 198 (reversing criminal convictions of various corporate and individual defendants because the FDA failed to comply with applicable statutory and regulatory requirements, which "grant[ed] . . . rights to the private citizens affected," rather than protect "the government by guidance of its officials"). *But see* United States v. Articles of Drug Promise Toothpaste for Sensitive Teeth, 594 F. Supp. 211 (N.D. Ill. 1984)(rejecting argument that a FDA Compliance Policy Guide barred the FDA's action to enjoin defendant from marketing its product but failing to discuss or even refering to the *Accardi* doctrine or any *Accardi*-doctrine cases).

88 A similar argument was made and rejected in Spillman v. United States, 413 F.2d 527 (9th Cir.), *cert. denied*, 396 U.S. 930 (1969). In *Spillman*, the defendant was convicted of mailing obscene materials. He argued that he should not have been convicted because a "memorandum letter circulated by the Department of Justice to the United States Attorneys . . . unofficially promulgated a policy of non-prosecution of offenders within a class within which [he fell]." *Id.* at 529. Without discussing the *Accardi* doctrine, the court rejected the argument.

> This court cannot inquire into the motives of the United States Attorney for prosecuting this appellant. The United States Attorney must be given wide latitude in order to effectively enforce the federal criminal laws. The policy which the appellant complains of is wholly voluntary in nature and is not founded on case law which would require this court to implement such a policy.

Id. at 530. This case is incorrect to the extent that it suggests that an agency must comply with its policies only if they are required by case law. *See, e.g.*, Morton v. Ruiz, 415 U.S. 199, 235 (1974)("Where the rights of individuals are affected, it is incumbent upon agencies to follow their own procedures. This is so even where the internal procedures are possibly more rigorous than otherwise would be required."). *But see Caceres*, 440 U.S. at 749 ("A court's duty to enforce an agency regulation is most evident when compliance with the regulation is mandated by the Constitution or federal law."). Moreover, there are cases which support the position that a policy of non-prosecution binds the government. *E.g.*, United States v. Falk, 479 F.2d 616, 621 (7th Cir. 1973)(vacating a conviction on selective prosecution grounds because defendant was prosecuted for exercising his first amendment rights, but also relying upon the government's failure to follow "its policy of non-prosecution" of certain individuals for failing to carry their draft cards; "it was incumbent upon the government . . . to explain why Falk was . . . singled out for prosecution in contravention of the government's own procedures"); Busche v. Burkee, 649 F.2d 509, 517 n.10 (7th Cir.)(dictum)(citing *Falk* for the proposition that courts can invalidate a decision to prosecute where there is a "governmental policy of non-prosecution"), *cert. denied*, 454 U.S. 897 (1981).

89 *See, e.g.*, Haitian Refugee Center v. Meese, 791 F.2d 1489, 1499-1500 (11th Cir.

In *Service v. Dulles*,[90] for instance, the Court invalidated petitioner's discharge from the Foreign Service because the Secretary of State violated State Department's regulations. The Court agreed with petitioner's claim that "regulations validly prescribed by a government administrator are binding upon [the administrator] as well as the citizen, and that this principle holds even when the administrative action under review is discretionary in nature."[91]

Similarly, in *Vitarelli v. Seaton*,[92] the Court reinstated a Department of the Interior employee who had been dismissed in a manner that failed "to conform to the procedural standards" set forth in rules promulgated in a departmental order by the Secretary of the Interior.[93] The Court held that, "as in *Service* [*v. Dulles*], [the Secretary] was bound by the regulations . . . even though without such regulations he could have discharged petitioner summarily."[94] The Court emphasized that "in proceedings of this nature," which lack the usual protections of "a cause being tried in a court of law before trained judges, scrupulous observance of departmental procedural safeguards is clearly of particular importance."[95]

Accardi, *Service v. Dulles*, and *Vitarelli* all involved application of the *Accardi* doctrine to civil agency action. In *Yellin v. United States*,[96] on the other hand, the Court applied the doctrine to reverse a conviction for criminal contempt. In *Yellin*, the House Committee on Un-American Activities was found to have "failed to exercise its discretion" according to guidelines set forth in one of its operating rules.[97] As a result, Yellin refused to answer certain questions, and he was convicted of contempt. Rejecting the argument that the rule

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1986); International House v. NLRB, 676 F.2d 906, 912 (2d Cir. 1982); Bills v. Henderson, 631 F.2d 1287, 1299 (6th Cir. 1980); NLRB v. Welcome-American Fertilizer Co., 443 F.2d 19, 20 (9th Cir. 1971)("When administrative bodies promulgate rules or regulations to serve as guidelines, these guidelines should be followed. Failure to follow such guidelines tends to cause unjust discrimination and deny adequate notice contrary to fundamental concepts of fair play and due process."); Hupart v. Board of Higher Educ. of the City of New York, 420 F. Supp. 1087, 1106 (S.D.N.Y. 1976)(Board obligated to comply with "an 'unwritten,' but unequivocal," policy. "The sweep of the doctrine is broad. Its applicability does not turn upon the formality of the embodiment of the pertinent policy."); *see also infra* note 123.

90 354 U.S. 363 (1957).

91 *Id.* at 372.

92 359 U.S. 535 (1959).

93 *Id.* at 539.

94 *Id.* at 540.

95 *Id.* Because the FDA's pre-indictment proceedings lack the usual protections afforded in courts of law, the FDA likewise should be held to a standard of "scrupulous observance of [agency] procedural safeguards." *Id.*

96 374 U.S. 109 (1963).

97 *Id.* at 120.

"was written to provide guidance for the Committee alone and . . . not . . . to confer [any rights] upon witnesses,"[98] the Court reversed Yellin's conviction and concluded that "[i]t is not too exacting to require that the Committee be [as] meticulous in obeying its own rules" as it was in "prepar[ing] the groundwork for prosecution in Yellin's case. . . ."[99]

In *Morton v. Ruiz*,[100] the Court confirmed that an agency's obligation to adhere to its own rules is not limited to rules set forth in formal regulations. The *Morton* Court reversed the Secretary of Interior's denial of general assistance benefits because, inter alia, the agency had failed to comply with the procedures set forth in its "manual," which was "an internal-operations brochure intended to cover policies that 'do not relate to the public.' "[101] The Court reasoned that

> [w]here the rights of individuals are affected, it is incumbent upon agencies to follow their own procedures. This is so even where the internal procedures are possibly more rigorous than otherwise would be required . . . . Before the [agency] may extinguish the entitlement of these otherwise eligible beneficiaries, it must comply, at a minimum, with its own internal procedures.[102]

Morton thus refutes the position that the FDA's prior-warning rule does not bind the agency because the relevant rule is not set forth in a formal regulation.[103]

In *United States v. Nixon*,[104] the Court again applied the *Accardi* doctrine in a criminal context. In rejecting President Nixon's refusal to respond to a subpoena duces tecum, the Court noted that the Attorney General had enacted a regulation giving the Special Prosecutor wide latitude in seeking relevant evidence. The Court held that the Attorney General must adhere to that regulation:

> Here, as in *Accardi*, it is theoretically possible for the Attorney General to amend or revoke the regulation defining the Special Prosecutor's authority. But he has not done so. So long as this regulation remains

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98 *Id.* at 115.

99 *Id.* at 124. *Yellin* refuted an argument that an individual could not challenge prosecution based upon the FDA's prior-warning policy unless he knew about and relied upon that policy in advance. "It was not until [Yellin's] trial . . . that it became apparent the Committee was violating its rules." *Id.* at 123. The Court nevertheless accepted Yellin's argument and reversed his conviction. "Yellin should be permitted the same opportunity for judicial review when he discovers at trial that his rights have been violated. . . . [His] reasonable expectation is that the Committee actually does what it purports to do, adhere to its own rules." *Id. But see infra* note 112.

100 415 U.S. 199 (1974).

101 *Id.* at 235.

102 *Id.* (citations omitted).

103 *But see infra* note 117.

104 418 U.S. 683 (1974).

> in force the Executive Branch is bound by it, and indeed the United States as the sovereign composed of the three branches is bound to respect and to enforce it.[105]

Three fairly recent Supreme Court decisions arguably signal a partial retreat from the broad sweep given to the *Accardi* doctrine in the above cases.[106] In the 1979 case of *United States v. Caceres*, the Court held that taped conversations recorded by the IRS were admissible in a defendant's criminal prosecution even though obtained in violation of agency regulations.[107] The Court reaffirmed the vitality of the *Accardi* doctrine,[108] but it was unwilling to apply it at the expense of relevant evidence in a criminal prosecution.[109] The decision no doubt resulted in large measure from the Court's displeasure with and disinclination to extend the exclusionary rule.[110] Furthermore, the IRS had "provided for internal sanctions in cases of knowing violations of the . . . regulations."[111] The FDA has no such violation. Nonetheless, *Caceres* adds new dimensions to the *Accardi* doctrine which would certainly be relied upon by the FDA and the United States Attorney's Office if the *Accardi* argument considered above were to be made.[112]

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105 *Id.* at 696 (citation omitted).

106 The Supreme Court has, however, cited the *Accardi* doctrine with approval in at least one recent case. *See* Black v. Romano, 471 U.S. 606, 622 n.18 (1985)(Marshall, J., concurring). Justice Marshall cited the doctrine as one of "numerous doctrines" which are "inform[ed] by the norm of regularity in governmental conduct." *Id.* (Marshall, J., concurring). Justice Marshall relied upon the doctrine to support the proposition that, "while the State can define the rules of punishment initially, choosing probation or imprisonment, the State cannot change the rules in the middle of the game." *Id.* at 621-22 (Marshall, J., concurring).

107 440 U.S. 741 (1979). *Cf. Heffner*, 420 F.2d at 813 (reversing a conviction that was based, in part, upon a statement obtained from a taxpayer by an IRS agent who failed to warn the taxpayer of the possibility of criminal prosecution, as required by an agency rule). *See infra* notes 126-31 and accompanying text.

108 *Caceres*, 440 U.S. at 751 n.14.

109 Justice Marshall filed a lengthy dissent criticizing the majority's departure from the Court's past insistence that agencies comply with "internal regulations [that] do not merely facilitate internal agency housekeeping, but rather afford significant procedural protections." *Id.* at 760 (Marshall, J., dissenting)(joined by Brennan, J.).

110 *See id.* at 754.

111 *Id.* at 756.

112 Particularly troubling are the Court's suggestion that the *Accardi* doctrine is somehow less applicable when "the agency was not required by the Constitution or by statute to adopt [the] procedures or rules" that the agency has failed to follow, *id.* at 749, and the Court's apparent introduction of a party's subjective reliance on the relevant regulation into the *Accardi* doctrine, *id.* at 752-53. As the dissent points out, these aspects of the opinion are totally foreign to, and inconsistent with, the Court's prior decisions. *E.g., Morton*, 415 U.S. at 235 ("it is incumbent upon agencies to follow their own procedures . . . even where [they] are possibly more rigorous than otherwise would be required"); *Yellin*, 374 U.S. at 123 (reversing a criminal contempt conviction because of non-compliance with a committee rule even though the convicted party did not know

The Court's 1981 decision in *Schweiker v. Hansen*[113] is also troubling. The *Hansen* Court held that the government was not estopped from denying petitioner retroactive benefits because a "field representative" of the Social Security Administration ("SSA") failed to comply with the instructions of an internal SSA handbook when interviewing the petitioner.[114] With the exception of *Caceres*, the Court failed to cite or discuss any of its *Accardi* cases. The facts of *Hansen* are plainly distinguishable from the hypothetical facts used in this Article, and the Court emphasized in *Hansen* the inappropriateness of estopping the government because of the negligence of a lower-level agent, especially when such estoppel would adversely affect the public treasury.[115] Nevertheless, the Court's refusal to attach significance to the agency's failure to follow its procedural rules supports a challenge to a party's reliance upon a policy statement contained in a FDA staff manual:

> [T]here is no doubt that [the field representative] failed to follow the Claims Manual. . . . But the Claims Manual is not a regulation. It has no legal force, and it does not bind the SSA. Rather it is a 13-volume handbook for internal use by thousands of SSA employees . . . . If [the] minor breach of such a manual suffices to estop [the Government], then the Government is put "at risk that every alleged failure by an agent to follow instructions to the last detail in one of a thousand cases will deprive it of the benefit of [other requirements] which experience has taught to be essential to the honest and effective administration of the Social Security Laws."[116]

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about the rule until trial and thus could not have relied upon it). *See supra* notes 96-103 and accompanying text. *Caceres* appears to be a result-oriented decision in which the majority conveniently, but inappropriately, disregarded numerous aspects of its *Accardi* precedent.

113 450 U.S. 785 (1981)(per curiam).

114 *Caceres*, 450 U.S. at 786, 790.

115 Like *Caceres*, *Hansen* appears to be a result-oriented decision.

116 *Caceres*, 450 U.S. at 789-90 (citations omitted). The Court's distinction between policy statements in an agency manual and policy statements set forth in regulations is inconsistent with past holdings. *See, e.g.*, *Morton*, 415 U.S. 199. Additionally, this Article argues that it is an inappropriate distinction to draw in most cases. A similar distinction was recently applied in Brock v. Cathedral Bluffs Shale Oil Co., 796 F.2d 533 (D.C. Cir. 1986)(opinion by Scalia, J.). In *Brock*, the court, in an opinion by then Circuit Judge Scalia, held that the Department of Labor's "Enforcement Policy and Guidelines for Independent Contractors," regarding the enforcement of the Federal Mine Safety and Health Act of 1977, 30 U.S.C. §§ 801-962 (1982), were not legally binding even though they had been published in the Federal Register. The court stated that, although "an agency must adhere to its own regulations," an agency "need not adhere to mere 'general statement[s] of policy.' " *Id.* at 536 (citations omitted). The *Brock* court held that there was "no basis for overturning the Secretary's judgment that his independent contractor enforcement guidelines do not constitute a binding, substantive regulation," because the guidelines were "replete with indications that the Secretary retained his discretion to cite production-operators as he saw fit." *Id.* at 538. The problem with the court's reasoning is that it largely defeats a central purpose of publishing guidelines: to

Additionally, the Court's decision in *Heckler v. Chaney*[117] arguably counters the view that a FDA failure to comply with its prior-warning policy would violate the *Accardi* doctrine and invalidate any subsequent criminal prosecution. As noted earlier, the Court held in *Chaney* that a decision by the FDA *not* to initiate enforcement actions is unreviewable under the APA because it constitutes "agency action [that] is committed to agency discretion by law."[118] The *Chaney* Court reversed the United States Court of Appeals for the District of Columbia Circuit, which had held that the FDA's inaction was reviewable, arbitrary and capricious.[119] The D.C. Circuit had based its decision principally upon the "strong presumption" of reviewability[120] and upon Supreme Court precedent to the effect that a matter is committed by law to agency discretion only "in those rare instances where the governing statute is 'drawn in such broad terms that in a given case there is no law to apply.' "[121] Significantly, the court of appeals held that there was "law to apply" in the form of a FDA policy statement which "made law to govern and guide [the FDA's] discretion in regulating the unapproved use of approved drugs."[122] The court cited the *Accardi* doctrine in a footnote as partial support for its conclusion that the FDA's policy statement was a binding agency "rule."[123] This rule, the circuit court concluded, provided part of the law that was available for the court to apply and subjected the FDA's inaction to judicial review.[124]

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ensure evenhandedness and consistency when agency officials exercise discretionary authority. The *Brock* court's holding essentially guarantees unlimited discretion to the Department of Labor in enforcing the Federal Mine Safety and Health Act. The result is inappropriate in a legal system that prides itself on achieving fairness and justice through various checks and balances. Moreover, the holding is inconsistent with many of the D.C. Circuit's earlier decisions. *E.g.*, Massachusetts Fair Share v. Law Enforcement Assistance Administration, 758 F.2d 708, 711 (D.C. Cir. 1985). In Massachusetts Fair Share, the court stated that the "settled" precept that "a federal agency must adhere firmly to self-adopted rules by which the interests of others are to be regulated . . . is rooted in the concept of fair play and in abhorrence of unjust discrimination, and its ambit is not limited to rules attaining the status of formal regulations." *Id.* Courts have applied this precept to statements in a "personnel manual," an "agency's 'usual practice,' " regulations "set forth in agency weekly bulletin," and "instructions . . . reported in agency news release." *Id.* It is interesting to note that then Circuit Judge Scalia dissented from the court in Massachusetts Fair Share, while writing the opinion for the court in *Brock*.

117 *Chaney*, 470 U.S. 821.

118 *See* 5 U.S.C. § 701(a)(2) (1982).

119 718 F.2d 1174 (D.C. Cir. 1983).

120 *Id.* at 1183-84.

121 *Id.* at 1184 (quoting Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 410 (1971)).

122 *Id.* at 1186.

123 *Id.* at 1186 n.31.

124 *Id.*

In reversing the court of appeals, the Supreme Court failed to address the applicability of the *Accardi* doctrine to the FDA's policy statement. The Court, however, did summarily reject the significance of the policy statement for reviewability purposes, in stating:

> We . . . find singularly unhelpful the agency "policy statement" on which the Court of Appeals placed great reliance. We would have difficulty with this statement's vague language even if it were a properly adopted agency rule. Although the statement indicates that the agency considered itself "obligated" to take certain investigative actions, that language did not arise in the course of discussing the agency's discretion to exercise its enforcement power, but rather in the context of describing agency policy with respect to unapproved uses of approved drugs by physicians. In addition, if read to circumscribe agency enforcement discretion, the statement conflicts with the agency rule on judicial review, 21 C.F.R. § 10.45(d)(2) (1984), which states that "[t]he Commissioner shall object to judicial review . . . if (i) [t]he matter is committed by law to the discretion of the Commissioner, e.g., a decision to recommend or not to recommend civil or criminal enforcement action . . . ." But in any event the policy statement was attached to a rule that was never adopted. Whatever force such a statement might have, and leaving to one side the problem of whether an agency's rules might under certain circumstances provide courts with adequate guidelines for informed judicial review of decisions not to enforce, we do not think the language of the agency's "policy statement" can plausibly be read to override the agency's express assertion of unreviewable discretion contained in the above rule.[125]

The Court's ambiguous language with respect to the agency's policy statement clearly runs counter to the position that the FDA's prior-warning policy binds the agency and must be complied with in routine cases if a criminal prosecution is to stand. The Court's actual holding, however, was limited to a finding that the policy statement at issue was inapposite and did not provide "law" for the district court to apply in evaluating the FDA's discretionary decision not to initiate enforcement actions. Therefore, *Chaney* does not—and *should* not—prevent lower courts from requiring the FDA to comply with its prior-warning policy in routine cases.

In this regard, one lower court decision also merits discussion. In *United States v. Heffner*,[126] the leading *Accardi* case in the Fourth Circuit, an agency had recommended a case to a United States Attorney for criminal prosecution, although the agency had failed to follow internal instructions which required the agency to give prior warnings to the regulated party. The defendant in *Heffner* was con-

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125 *Chaney*, 470 U.S. at 836.

126 420 F.2d 809 (4th Cir. 1969).

victed of criminal tax fraud based, in part, upon statements that he gave to an IRS special agent. Contrary to internal instructions, this agent failed to warn the taxpayer that the agent's function was "to investigate the possibility of a criminal prosecution" and that the taxpayer could obtain counsel before talking to the agent.[127] The relevant instructions were contained in an IRS "News Release" and were intended to "insure uniformity in protecting the Constitutional rights of all persons."[128] Applying the *Accardi* doctrine, the court held that it was reversible error to admit into evidence statements obtained in violation of internal procedures. The court stated:

> An agency of the government must scrupulously observe rules, regulations, or procedures which it has established. When it fails to do so, its action cannot stand and courts will strike it down. . . . It is of no significance that the procedures or instructions which the IRS has established are more generous than the Constitution requires. . . . Nor does it matter that these IRS instructions to Special Agents were not promulgated in something formally labeled a "Regulation" or adopted with strict regard to the [APA]; the *Accardi* doctrine has a broader sweep. . . . [This strict adherence is] consistent with the doctrine's purpose to prevent the arbitrariness which is inherently characteristic of an agency's violation of its own procedures. . . . The arbitrary character of such a departure is in no way ameliorated by the fact that the required procedure was enunciated as an instruction in a "News Release."[129]

The *Heffner* court reversed the taxpayer's conviction and remanded for further proceedings. It suggested, however, that because the taxpayer had already served most of his sentence, "this may be a case in which the government concludes to dismiss the indictment."[130] This aspect of the opinion supports the position that a FDA violation of the *Accardi* doctrine could warrant dismissal of a

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127 *Id.* at 811 (citation omitted).

128 *Id.*

129 *Id.* at 812 (citations omitted). *See also* United States v. Leahey, 434 F.2d 7 (1st Cir. 1970), in which the court suppressed statements obtained by the IRS from a taxpayer because of the agent's failure to comply with the prior-warning instructions involved in *Heffner*.

130 Heffner, 420 F.2d at 813. The Supreme Court's 1979 decision in *Caceres*, *supra* notes 107-16 and accompanying text, clearly undermines *Leahey*, *supra* note 129, and, to a lesser extent, *Heffner*, *see supra* notes 126-29 an accompanying text. The Court held in *Caceres* that taped conversations were admissible even though obtained by the IRS in violation of agency regulations. The regulations at issue in *Caceres*, however, were different from those involved in *Heffner* and *Leahey*, and the *Caceres* Court expressly reaffirmed the vitality of *Accardi* doctrine. The majority opinion in *Caceres* did not mention *Heffner* or *Leahey*. *But see Caceres*, 440 U.S. at 758 n.16 (Marshall, J., dissenting)(citing both *Heffner* and *Leahey* as correctly noting the "due process foundations" of the *Accardi* doctrine). Nevertheless, the FDA and the United States Attorneys probably would argue that *Heffner* is no longer good law in light of *Caceres*. *See Groder*, *supra* note 131; United States v. Irvine, 699 F.2d 43, 46 (1st Cir. 1983).

subsequent indictment by the United States Attorney.[131]

IV. SUMMARY

This Article has highlighted the important, but often overlooked, role that administrative agencies play in the criminal enforcement of federal statutes. Substantial legal issues are raised, and rights implicated, by the exercise of discretion by administrative agencies, particularly when an abuse of that discretion could result in criminal penalties. Courts should vigorously guard against agency abuses of discretion in referring cases for criminal prosecution. Under the hypothetical situation used in this Article, a court should dismiss an attempted criminal prosecution of a routine FDA violation if the FDA failed to comply with its prior-warning policy. Such a prosecution would be inconsistent with the *Accardi* doctrine

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131 The Fourth Circuit's decision in *Hefner* must be considered in light of *Groder v. United States*, which affirmed a district court's denial of a motion to squash certain IRS summonses. In *Groder*, the appellant had argued that "the IRS violated [his] due process rights by failing to follow its own administrative procedures [contained in the IRS Manual] governing referral of a taxpayers case for [criminal] fraud investigation." *Groder*, No. 86-2054, slip op. at 2. The Fourth Circuit rejected this argument. Relying principally on *Caceres*, the court "distinguish[ed] internal rules of agency procedure from regulations promulgated pursuant to statutory directive for a taxpayers benefit." *Id.* at 6. The court suggested, in dictum, that "the judmental nature of the referral decision [should not be transformed] into one with general *a priori* rules and conditions.... *Id.* at 10. The court failed to cite *Accardi*, *Hefner* or any of its other *Accardi* decisions, however, and its opinion in *Groder* may be one which should be limited to its particular facts. This Article asserts that courts must apply the *Accardi* doctrine rigorously, erring perhaps on the side of its application, to ensure that agencies refer criminal cases rationally and evenhandedly. With the arguable exception of *Groder*, the Fourth Circuit has consistently applied the *Accardi* doctrine in that manner. *See, e.g.*, Jones v. Board of Governors of the University of North Carolina, 704 F.2d 713, 717 (4th Cir. 1983); Morris v. McCaddin, 553 F.2d 866, 870 (4th Cir. 1977)(invalidating a reduction in force by the Army National Guard that was not accomplished in accordance with "general guidance" that was provided in a pamphlet distributed to various Adjutant Generals at a meeting in Washington, D.C.); Elec. Components Corp. of North Carolina v. NLRB, 546 F.2d 1088, 1090 (4th Cir. 1976); McCourt v. Hampton, 514 F.2d 1365, 1370 (4th Cir. 1975)(invalidating an Army transfer and demotion that did not comply with an "internal regulation" contained in the Federal Personnel Manual. "This court has been and will be as assiduous in requiring the government to live up to regulations for the conduct of its own affairs when noncompliance results in prejudice to an adverse party, as it has and will continue to be in requiring a private citizen to regulate and conduct himself in accordance with federal law" (citation omitted)); Cross v. United States, 512 F.2d 1212, 1217-18 n.8 (4th Cir. 1975)(en banc)(holding that a district court has jurisdiction to review the severity of administrative sanctions and noting that instructions contained in a memorandum to regional and field offices addressed the question of sanctions; "excessive variance, something more striking than 'mere unevenness,' would be evidence of arbitrary or capricious action, because . . . it may well be concluded that the Secretary [of Agriculture] failed to observe his own regulations and therefore the sanction was unwarranted in law"); United States *ex rel.* Brooks v. Clifford, 409 F.2d 700, 706 (4th Cir. 1969).

and its underlying due process and administrative law principles and would constitute dissimilar treatment of similarly situated parties in violation of the prohibition against arbitrary and capricious agency action. Moreover, prosecution under such facts could rise to the level of discriminatory and selective enforcement by the FDA in violation of the due process and equal protection requirements.

The legal rights of potential defendants will necessarily be colored in a given case by the severity of the alleged FDA violation, and reviewability problems will certainly arise. Nevertheless, corporate and individual defendants may be able to advance legal arguments for non-prosecution based upon the FDA's involvement in the criminal prosecution. These legal arguments are available when the FDA (or any agency, for that matter) has failed to treat similarly situated parties in a consistent manner, or when it has failed to comply with an agency policy or rule whose application is intended to protect the rights of individuals subject to possible criminal prosecution. As the Supreme Court stated in *Yellin*, "[i]t is not too exacting to require that [a federal agency] be [as] meticulous in obeying its own rules [as it is in] prepar[ing] the groundwork for prosecution in [each] case."[132] It is essential that courts recognize the potential for agency abuse of discretion in the context of the criminal enforcement of federal statutes, and that they hold agencies strictly to the requirements of consistent treatment and compliance with the agencies' own rules.

[132] *Yellin*, 374 U.S. at 124.