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An Examination of Strict Criminal Liability Under the Food, Drug and Cosmetic Act of 1938: Is It Time For Change?

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Part I

Introduction

Food and drug violations have been largely governed by a strict liability standard since the nineteenth century. Use of this standard in connection with criminal sanctions has generally been defended on the grounds that the health and welfare of the public are of such importance that it is necessary to provide members of the food and drug industry with an extra impetus to abide by the applicable food and drug regulations.

Nonetheless, strict criminal liability has not been wholly successful in averting violations of food and drug regulations, as evidenced by the presence of a number of criminal cases involving food and drug industry participants. It, therefore, might be time to question the goals of the Food, Drug and Cosmetic Act of 1938, enforcement policy, and whether the use of strict criminal liability is a necessary method of achieving those goals in the current setting.

This paper attempts to analyze these questions by tracing the history of strict liability in the area of food and drug law violations**,** discussing the common arguments in favor and against the imposition of strict liability in that context, and exploring alternative regimes given the current state of affairs.

Part II

Evolution of Strict Criminal Liability in the Food and Drug Industry

Strict liability for food and drug violations is rooted in nineteenth century English law. In 1846, the Court of Exchequer in *Regina v. Woodrow* held a man liable for having adulterated tobacco in his possession even though he proved that he had no knowledge that the tobacco was not genuine. The rationale for the Court's decision was that, even though innocent men might suffer for not having examined the goods in their possession, public inconvenience would be greater if knowledge of the adulteration had to be proven in every case.[1] *Regina v. Woodrow* was followed by a number of decisions regarding the unknowing sale of adulterated food. Around the same time, decisions in the United States began to appear which dispensed of the mens rea requirement in the case of certain regulatory violations.[2] In *Commonwealth v. Boyton* (1861), the Massachusetts court found the defendant guilty of selling intoxicating liquor without proof of his knowledge that the liquor was intoxicating. The court's rationale for the decision was simply that the statutory prohibition against the sale of intoxicating liquors did not require proof that the defendant knew the illegal character of his act.[3] This was followed by several more cases in Massachusetts involving food adulteration and, by the late 1860's, the public welfare offense doctrine became widely recognized in all states.[4]

[1] Sayre, *Public Welfare Offenses*, 33 Colum. L. Rev. 55, 56-58 (1933).

[2] *Id.* at 62-66.

[3] Judge Hoar stated: "Where the act is expressly prohibited, without reference to the intent or purpose, and the party committing it was under no obligation to act in the premises, unless he knew he could do so lawfully, if he violates the law he incurs the penalty." *Commonwealth v. Boynton*, 83-84 Mass. 160 (1861).

[4] Sayre, *supra* at 62-66.

In the mid-nineteenth century, food commerce expanded across the country creating the impetus for food and drug regulation. In December 1879, G.W. Wigner won the National Board of Trade's "$1000 Competition for the Draft of a Food Adulteration Act" and his definition of food adulteration was ultimately incorporated in the Federal Food and Drugs Act of 1906 ("Act of 1906).[5] In 1880, Peter Collier, the Chief Chemist of the Division of Chemistry in the United States Department of Agriculture, recommended that a national food and drug law be enacted. In his report, he stated:

"Laws should be made and vigorously enforced making the adulteration of foods and medicines a criminal offense. Where life and health are at stake no specious arguments should prevent the speedy punishment of those unscrupulous men who are willing, for the sake of gain, to endanger the health of unsuspecting purchasers."[6]

Subsequently, Dr. Harvey W. Wiley, head of the Division of Chemistry, completed an investigation into food and drug adulteration which ultimately culminated in the enactment of the Act of 1906.[7] The principle reasons for its enactment were to protect the public and to secure fair trade in commerce.[8]Under the

[5]Peter Barton Hutt and Peter Barton Hutt II, *A History of Government Regulation of Adulteration and Misbranding of Food*, 39 Food Drug Cosm. L.J. 2, 47-51 (1984).

[6]Charles Wesley Dudd, *Its Legislative History*, *in* HISTORIC MEETING TO COMMEMORATE FORTIETH ANNIVERSARY OF ORIGINAL FOOD AND DRUGS ACT 9,20 (Commerce Clearing House, Inc., 1946).

[7]In an 1898 report, Dr. Wiley stated: "The necessity of national legislation on this subject has long been apparent, for it is evident that state laws, however excellent and well enacted, cannot realize their full purpose without the supplement of federal legislation." *Id.* at 21.

See also S. Rep. 972, at 1-3, 57^{th} *Cong.,* 1^{st} *sess.* (1902) for history leading up to the passage of the Act of 1906.

[8]In *H.R. Rep.* 381, at 5-6, 58^{th} *Cong.,* 2^{nd} *sess.* (1904), the Committee on Interstate and Foreign Commerce submitted the following statement under the heading "Some Reasons for Passage of the Bill":

"... [A]dulteration of food of a harmful character is prevalent to an alarming extent, and..., inspired by cupidity, these adulterations are rapidly increasing, so that in many classes of foods it is almost impossible to procure a pure article.

...

We do not assume that the provisions of this act will constitute a perfect remedy, but we

Act of 1906, anyone manufacturing adulterated or misbranded foods or drugs would be fined not more than five hundred dollars or sentenced to one year imprisonment, or both, and anyone committing a subsequent offense would be fined at least one thousand dollars or sentenced to one year imprisonment, or both.[9] Furthermore, anyone introducing, making interstate shipments, or selling adulterated or misbranded foods or drugs would be fined no more than two hundred dollars, and anyone committing a subsequent offense would be fined no more than three hundred dollars or be sentenced to no more than one year imprisonment, or both.[10]

Case law under the Act of 1906 indicates that judges moved from applying strict criminal liability for violations to requiring some intent on the part of the alleged violators. In the earlier cases, it was argued that the Act of 1906 was

do believe that there is herein a wise beginning and with experience and observation, with larger opportunities for study, with greater familiarity with the many complex phases of the subject, future committees and Congresses will be able to do much more toward eradication of a recognized and widely prevailing evil.

We believe that everyone recognizes the necessity of governmental regulations to prevent the sale of adulterated, poisonous, or other injurious food products. The sand with which our forefathers are reputed to have adulterated their sugar, while a fraud upon the purchaser, was doubtless comparatively harmless. The adulterations of the present day are neither so clumsy or, as a rule, so harmless. The ingenuity of man has been busy during the past half century in devising new forms of machinery, new methods of commercial enterprise, new ideas, and new things in every branch and walk of life, including new processes of cheapening the cost of production of articles of food, drink, and drug by the use of mixtures, adulterants, and preservatives.

In so far as these are harmless and can not be a fraud upon the purchaser or user they may be of great benefit, but the ingenuity of man in providing either the adulteration or preservative of food products by the use of substances harmful to the human system in their character must be met by government restraint....

... [The Act of 1906] is designed to protect and aid the manufacturer, the wholesale dealer, the retail dealer, and the consumer. It aims to combine protection for the people with as little injury to legitimate business as possible.

..."

[9] 21 U.S.C. §1 (1906).

[10] 21 U.S.C. §2 (1906).

intended to safeguard the public and that the only question to be determined was whether the Act was violated rather than whether the defendant intended to violate the law.[11] These cases all held that the defendants were guilty of violating the Act of 1906 so long as the article was in fact adulterated or misbranded. However, in later cases under the Act of 1906, it was argued that in order to impose criminal liability on a defendant he must have had knowledge or reason to know of the violation.[12] Legislative history seems to suggest that Congress intended strict liability to apply to violations of the Act of 1906. At Congressional meetings held before the passage of the Act of 1906, various speakers voiced concerns about the imposition of criminal penalties when the language of the pertinent penalty section did not include the words "knowingly" and "willfully". One speaker argued that allowing the imposition of criminal penalties in the absence of knowledge and willfulness is "vicious" and "may place innocent men in a perfectly helpless position". Another speaker argued

[11] *U.S. v. Gidden*, S.D.N.Y. (1912). *See also*, *U.S. v. Griebler*, E.D.Ill. (1908) (holding that in determining whether a defendant who shipped adulterated milk is guilty of violating the Act of 1906, the only issue is whether the milk was in fact adulterated and not whether the defendant himself adulterated the milk or knew that the milk was adulterated); *U.S. v. Weeks*, S.D.N.Y. (1913) (holding that whether or not the defendant intended to ship poison is immaterial but rather the question is simply whether he in fact shipped the poison); *U.S. v. Glaser, Kohn & Co.*, N.D.Ill. (1914) (holding that in finding the defendant guilty, it was unnecessary "to show that the defendant intentionally put up an adulterated article, or that the defendant knew at the time it turned this article over to [the dealer] that the article was adulterated" and that the only question was whether it was adulterated at the time it was turned over to the dealer).

[12] *U.S. v. Bowers*, E.D.Tenn. (1916) (holding that under the Act of 1906, if a defendant does an act "without knowledge of the fact that otherwise makes it unlawful, unless he had knowledge of the fact or facts that brought knowledge home to him, then he is not guilty" and that unless a defendant had reason to know an article was misbranded or adulterated "he would not be guilty under the criminal law"). *See also, U.S. v. Tetz*, W.D.Wash. (1919) (holding that the defendants could only be convicted if they intentionally adulterated the milk and the effect of the adulteration was to reduce or injuriously affect its quality or strength, or if they intended to deceive purchasers into buying an inferior product); *U.S. v. Marmarelli*, S.D.N.Y. (1924) (holding that the defendants could only be convicted if they "knowingly or intentionally" shipped the adulterated oil; Judge Clayton stated: " I do not think that the law contemplates that a man was violating the law when he had no intention whatever to violate the law").

that the law could make criminals out of honest citizens and in so doing destroy their reputation and character. These concerns were not directly responded to, but rather it was stated that commerce would be benefitted if all participants adjusted themselves to conducting business on an honest basis, and that innocent participants had nothing to fear.[13] It would seem that after hearing these concerns and making a conscious decision not to include the words "knowingly" and/or "willfully" in the penalty section of the Act of 1906, Congress intended strict liability to apply in order to further its end of achieving complete honesty in commercial dealings. One could make the argument that Congress did not intend strict liability to apply given that its application would inevitably result in some 'innocent' men being found guilty of crimes, and it had clearly stated that honest dealers did not have to fear criminal liability. If the latter argument were accurate, however, there is reason to believe that, when the Act of 1906 was revised (as discussed below), Congress would have altered the language of the penalty section to ensure that courts did not apply a strict liability standard. Yet, no such alteration was made.

Enforcement of the Act of 1906 was originally carried out by the Bureau of Chemistry. However, when the regulatory duties of the Bureau became too

[13] *S. Rep.* 972, at 14-17, 46-49, 57^{th} *Cong.,* 1^{st} *sess.* (1902).

See also H.R. Rep. 2118, at 7, 59^{th} *Cong.,* 1^{st} *sess.* (1906), wherein Mr.Mann, from the Committee on Interstate and Foreign Commerce, stated:

" The penalties of the bill are aimed at cheats. That which is forbidden is the sale of goods under false pretenses, or the sale of poisonous articles as good food. No honest dealer need fear any provision in the bill. Legitimate trade should welcome its enactment into law. Only those wishing to deceive the public will object to its provisions."

burdensome, its law enforcement organization was incorporated in a new bureau originally referred to as the Food, Drug, and Insecticide Administration and later known as the Food and Drug Administration ("FDA").[14] Soon after the FDA's formation, the Administration sought revision of the Act of 1906.[15] This culminated in the passage of the Federal Food, Drug, and Cosmetic Act of 1938 (the "Act) which included many features of the Act of 1906 but sought to make some improvements.[16] The principal aim of the Act, like the Act of 1906, was to protect the general welfare of the population.[17] The Act retained criminal liability for violations of its provisions. Specifically, the Act provides that anyone who commits any violations under the Act (i.e., anyone who introduces adulterated or misbranded foods, drugs, cosmetics or medical devices into

[14]Paul B. Dunbar, *Its Administrative Progress*, *in* HISTORIC MEETING TO COMMEMORATE FORTIETH ANNIVERSARY OF ORIGINAL FOOD AND DRUGS ACT 51, 60 (Commerce Clearing House, Inc., 1946).

[15]The *Report of the Chemist* stated:

"While the accomplishments of the Food and Drugs Act have been considerable, it must be admitted that it has its serious limitations. Especially conspicuous ones are the lack of legal standards for foods, of authority to inspect warehouses, and of any restriction whatever upon the use of many of the most virulent poisons in drugs; the limitations placed upon the term 'drugs' by definition which render it difficult to control injurious cosmetics, fraudulent mechanical devices used for therapeutic purposes, as well as fraudulent remedies for obesity and leanness; the limitation of dangerous adulterants to those that are added so that the interstate shipment of a food that naturally contains a virulent poison is unrestricted. Furthermore, the law fails to take cognizance of fraudulent statements covering foods or drugs which are not in or upon the food or drug package."

J. Howard McGrath, *A Fundamental Law of the Law, in* HISTORIC MEETING TO COMMEMORATE FORTIETH ANNIVERSARY OF ORIGINAL FOOD AND DRUGS ACT 81, 86 (Commerce Clearing House, Inc., 1946).

[16]*S. Rep.* 361, at 2, *74th Cong., 1st sess.* (1935) stated:

"The bill now contains all features of the present law that have proved valuable through the 28 years of its enforcement, in promoting honesty and fair dealing in the sale of foods and drugs. Its principal differences from the present law lie, first, in the elimination of those provisions whose terms have compelled the courts to reach interpretations that have afforded avenues of escape for the unscrupulous; second, extension of its provisions to false advertising and to harmful or falsely represented cosmetics; third, amplification and reinforcement of the provisions designed to safeguard the public health and to promote honesty and fair dealing; and fourth, strengthening its procedural provisions better to effectuate its purpose."

[17]Watson B. Miller, *Its Social and Economic Aspects, in* HISTORIC MEETING TO COMMEMORATE FORTIETH ANNIVERSARY OF ORIGINAL FOOD AND DRUGS ACT 139, 140 (Commerce Clearing House, Inc., 1946).

interstate commerce) "shall be imprisoned for not more than one year or fined not more than one thousand dollars, or both", and that anyone who commits another such violation after a previous conviction has become final or commits a violation with intent to defraud or mislead "shall be imprisoned for not more than three years or fined not more than ten thousand dollars, or both."[18]

Although legislative history is scant on this particular point, case law under the Act(see Part III) suggests that underlying the imposition of strict criminal liability for violations of the Act was the thought that as between the people who choose to participate in the food and drug industry, and the innocent members of society who depend on those people to ensure the safety of the food and drug supply, the burden of compliance with the Act should be placed on the former group. Deterrence is also best achieved through individual liability rather than corporate fines which might simply be viewed as a cost of doing business.[19] Furthermore, without criminal enforcement of violations, industry participants might tread closer to the outer limits of compliance and into the realm of violative conduct rather than remaining clearly within the bounds of compliance.[20] Thus, in the interest of the larger good and to ensure adequate incentives for compliance, criminal liability has been permitted to attach when

[18] Federal Food, Drug and Cosmetic Act §303(a)(1996).

[19] James T. O'Reilly, FOOD AND DRUG ADMINISTRATION §8.01 (2^{nd} ed. 1993).

[20] "We are all aware that some businesses and individuals seek to walk a fine line between compliance with the law and violative conduct and, thereby, to achieve a savings of money and effort that more publicly responsible individuals and businesses deliberately invest to assure compliance. Such conduct is unacceptable..." Remarks of Eugene Pfeifer, Associate Chief Counsel for Enforcement, FDA, to the Food and Drug Law Institute (Mar. 16, 1976).

there is no criminal intent and sometimes even no awareness of the occurrence of a violation.

Part III

Case History

A. *The "Responsible Relation" Standard*

In 1943, it became apparent that the government would be willing to apply strict criminal liability to violations of the Act. In the *Dotterweich* case decided that year,[21] the Supreme Court held Joseph Dotterweich personally criminally liable under the Act for introducing adulterated drugs into interstate commerce even though he did not personally commit the violative act, he did not authorize the act to be committed, and was not even aware that the act had been committed. Dotterweich was general manager of Buffalo Pharmacal Company, Inc., a corporation which bought drugs from a wholesale manufacturer, then repackaged them for shipments to an out-of-state physician. Dotterweich was prosecuted based on three of these shipments. Dotterweich had "no personal connection with either shipment but he was in general charge of the corporation's business and had given general instructions to its employees to fill orders

[21] *U.S. v. Dotterweich*, 320 U.S. 277 (1943).

received from physicians."[22] The jury found him guilty and he was fined $500 on each count, with payment suspended on the second and third counts, and was given probation for sixty days on each count to run concurrently.[23] The appellate court reversed on the basis that Dotterweich was not a "person" within the meaning of the Act.[24] The Supreme Court, however, reversed the judgement of the appellate court and reinstated Dotterweich's conviction.[25] As to strict liability under the Act, Justice Frankfurter stated:

"The purposes of [the Act] thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection... The prosecution to which Dotterweich was subjected is based on a now familiar type of legislation whereby penalties serve as effective means of regulation. Such legislation dispenses with the conventional requirement for criminal conduct - awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger... Hardship there doubtless may be under a statute which thus penalizes the transaction though consciousness of wrongdoing be totally wanting. Balancing relative hardships, Congress has preferred to place it upon those who have at least the opportunity of informing themselves of the existence of conditions imposed for the protection of consumers, rather than to throw the hazard on the innocent public who are wholly hapless."[26]

As to who should fall in the category of those "standing in responsible relation to a public danger", Justice Frankfurter went on to state:

"It would be too treacherous to define or even to indicate by way of illustrations the class of employees which stands in such a responsible relation... In such matters the good sense of prosecutors, the wise guidance of trial judges, and the ultimate judgment of juries must be trusted."[27]

[22] *U.S. v. Buffalo Pharmacal Co., Inc.*, 131 F.2d 500, 501 (2d Cir. 1942).
[23] 131 F.2d at 501.
[24] 131 F.2d at 503-504.
[25] 320 U.S. 277.
[26] 320 U.S. at 280-285.
[27] 320 U.S. at 285.

After *Dotterweich*, it was apparent that the government would impose strict individual criminal liability under the Act even in the absence of direct participation in the violative conduct, but there remained an open-ended question as to how far within, and possibly beyond, the corporate structure that liability would extend.

In *United States v. Parfait Powder Co.,*[28] it became evident that the court would recognize vicarious criminal liability under the Act.[29] In that case, the defendant entered into a contract with another company, Helfrich Laboratories, whereby Helfrich agreed to manufacture, package and distribute hair lacquer pads to the defendant's customers. The arrangement was such that the defendant was to supply Helfrich with all of the necessary materials and Helfrich was to then impregnate the pads with a shellac lacquer, place them in labeled jars bearing the defendant's name, and ship the packages as directed by the defendant. Without the defendant's knowledge, Helfrich substituted a gum for the shellac in the lacquer. The gum rendered the pads deleterious when used in accordance with the label directions. The defendant forbade continued use of the gum as soon as it was made aware of the substitution.[30] The defendant was convicted of introducing adulterated cosmetics into interstate commerce,

[28] *U.S. v. Parfait Powder Co.*,163 F.2d 1008 (7^{th} Cir. 1947), cert. denied, *Parfait Powder Co. v. U.S.*, 332 U.S. 851 (1948).

[29] Although there was no individual defendant in this case, it has been frequently cited for the proposition of absolute and vicarious criminal liability under the Act. Daniel F. O'Keefe Jr. and Marc H. Shapiro, *Personal Criminal Liability Under the Federal Food, Drug and Cosmetic Act - The Dotterweich Doctrine*, 30 Food Drug Cosm. L.J. 11 (Jan. 1975).

[30] 163 F.2d at 1009.

but on appeal argued that Helfrich was an independent contractor for whom the defendant was not responsible. The court responded:

"... we are not concerned with any distinction between independent contractors and agents in the ordinary sense of those words... [The defendant] saw fit to create out of Helfrich's activities in its behalf an instrumentality and to avail itself of the acts of that instrumentality, which effected an introduction into commerce of an adulterated article violative of the standards fixed by the Act... The liability was not incurred because defendant consciously participated in the wrongful act, but because the instrumentality is controlled in the interest of public policy by imputing the act to its creator and imposing penalties on the latter."[31]

To summarize its position on vicarious liability, the court stated:

"... one who owes a certain duty to the public and entrusts its performance to another, whether it be an independent contractor or agent, becomes responsible criminally for the failure of the person to whom he has delegated the obligation to comply with the law, if the nonperformance of such duty is a crime."[32]

In *Golden Grain Macaroni Co. v. United States*[33], it became evident that the court would further extend personal criminal liability to individuals who were far removed from the premises where the violations took place. In that case, Dedomenico, the president and general manager of Golden Grain Company's Seattle plant, was convicted for causing adulterated foods to be introduced into interstate commerce and sentenced to pay a $5000 fine.[34] Dedomenico argued that he could not be held responsible for the shipments due to the fact that he was in California and thus absent from the plant during the inspections which uncovered the violations. The Ninth Circuit rejected this argument noting that the unsanitary conditions had been present for a considerable length of time prior to Dedomenico's departure and that he had suffered a previous similar conviction under the Act, but stating more importantly that "criminal

[31] 163 F.2d at 1009.
[32] 163 F.2d at 1010.
[33] *Golden Grain Macaroni Co., Inc. v. U.S.*, 209 F.2d 166 (9^{th} Cir. 1953).
[34] 209 F.2d at 166-167.

responsibility of a corporate officer having broad authority such as that possessed by [Dedomenico] does not depend upon his physical presence."[35] Thus *Golden Grain* went one step further than *Dotterweich* in imposing strict criminal liability on a corporate who not only had no personal connection with the introduction of adulterated products, but who was also physically far removed from the premises and thus not even theoretically able to monitor all happenings at the premises in which the violations took place.

United States v. Shapiro[36] reaffirmed the principle that physical presence is unnecessary for conviction under the Act under even more tenuous circumstances. In that case, Shapiro, as president and sales manager of Tasty Cookie Company, pled guilty to four counts involving violations under the Act and *nolo contendre* to another count. He was fined $300 and given a probated two-year sentence. During this probationary period, Shapiro decided to sell the company and found a purchaser; during the negotiations, the purchasing company hired another man to take over Tasty's production. Just prior to the sale closing, the Tasty plant was inspected and found to be infested with vermin. After a hearing, the district court found that Shapiro had violated probation and sentenced him to six months incarceration. Shapiro argued that he was not responsible for the violations due to the fact that equitable title had already passed to the purchaser and thus he was not a "responsible officer" of the company when the

[35] 209 F.2d at 168.
[36] *U.S. v. Shapiro*, 492 F.2d 335 (6^{th} Cir. 1973).

violations were discovered.[37] The Sixth Circuit found, however, that Shapiro held the same corporate title as president on the date of the inspection as he had held when he entered the original guilty pleas, and was thus responsible. The court stated:

> "... Shapiro had the power and the authority to devise whatever measures were necessary to assure compliance with the FDA regulations... He could have shut down the plant until the company was sold and new ownership could assume complete and unobstructed control. He could have required [the purchaser]... to assure that adulterated food products from the Tasty plant would not be made available to the consumer. Or he could have completely and adequately cleaned the plant."[38]

The Sixth Circuit also reiterated that "neither physical presence nor personal participation is required for a finding of criminal responsibility under the Act."[39]

2. The "Foresight and Vigilance" Standard and the "Objective Impossibility" Defense

In *United States v. Wiesenfeld Warehouse Company,*[40] the Supreme Court hinted that a defense to criminal charges for violations of the Act may be allowed by "one who is, by the very nature of his business powerless to protect against... contamination, however high the standard of care exercised."[41] In that case, however, the Court was more concerned with another issue related to the construction of the Act. The availability and application of an "impossibility defense" was not fully addressed again until the *Park* and *New England Grocer Supply Company* cases over a decade later.

[37] 492 F.2d at 336.
[38] 492 F.2d at 337.
[39] 492 F.2d at 337.
[40] *U.S. v. Wiesenfeld Warehouse Co.*, 376 U.S. 86 (1964).
[41] 376 U.S. at 91.

The *Park* case[42] presented another opportunity for the Supreme Court to address the issue of criminal liability under the Act. Park was president and chief executive officer of Acme Market, Inc., a national retail food chain with approximately 36,000 employees, 874 retail outlets, and 16 warehouses. Park's office was at corporate headquarters in Philadelphia, PA. In April 1970, the FDA advised Park of unsanitary conditions in the Philadelphia warehouse. In 1971, the FDA found similar conditions existing in the Baltimore warehouse. These conditions remained and in 1972, the FDA advised Park of the conditions in the Baltimore warehouse. In a subsequent inspection, similar conditions were again found in the Baltimore warehouse and Park was charged with violations of the Act, to which he pled not guilty. Park testified that Acme had an "organizational structure for responsibilities for certain functions" and that different aspects of operations were "assigned to individuals who, in turn, have staff and departments under them". He stated that the vice president for legal affairs informed him that the Baltimore division vice president was taking care of the unsanitary conditions situation. Park did not think that he could have done anything more than what was already being done to correct the situation. Nevertheless, the jury found Park guilty and he was fined $50 on each count of the five counts brought against him.[43] The appellate court reversed the conviction and remanded for a new trial due to the fact that the trial court's jury

[42] *U.S. v. Park*, 421 U.S. 658 (1975).
[43] 421 U.S. at 661-665.

instructions might have left the jury with the impression that Park could be found guilty without any wrongful action on his part, and that proof of this element was required by due process.[44] The Supreme Court granted certiorari to address the standard of liability of corporate officers under the Act.

The Court reiterated its position that the highest standard of care should be imposed upon industry officials given the public interest in safe foods. The Court stated:

> "Thus Dotterweich and the cases which have followed reveal that in providing sanctions which reach and touch the individuals who execute the corporate mission - and this is by no means necessarily confined to a single corporate agent or employee - the Act imposes not only a positive duty to seek out and remedy violations when they occur, but also, and primarily, a duty to implement measures that will insure that violations will not occur. The requirements of foresight and vigilance imposed on responsible corporate agents are beyond question demanding, and perhaps onerous, but they are no more stringent than the public has right to expect of those who voluntarily assume positions of authority in business enterprises whose services and products affect the health and well-being of the public that supports them."[45]

The standard presented by the Court in *Dotterweich* (i.e., placing the burden of acting on people who are otherwise innocent but are "standing in responsible relation to a public danger") was strengthened, or at least better defined, by the *Park* Court which affirmatively required "foresight and vigilance" to ensure that violations do not occur. More importantly, however, the *Park* Court recognized that a corporate agent would be able to defend himself against charges under the Act if it was "objectively impossible" for the agent to prevent the violations from occurring.

> "... the Act, in its criminal aspect, does not require that which is objectively

[44] 421 U.S. at 666.
[45] 421 U.S. at 672.

impossible... The theory upon which 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.'"[46]

In sum, the Court stated:

"... the Government establishes a prima facie case when it introduces evidence sufficient to warrant a finding by the trier of facts that the defendant had, by reason of his position in the corporation, responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of, and that he failed to do so... [If the defendant offers an impossibility defense], the Government [is] required to prove beyond a reasonable doubt that [the defendant] was not without the power or capacity to affect the conditions which founded the charge..."[47]

In a case decided only two years later, *United States v. Starr*[48], it became clear that the "foresight and vigilance" standard articulated in *Park* would operate as a very strict standard. In that case, Dean Starr, secretary treasurer of Cheney Brothers Food Corporation, was charged with three counts of violating the Act by allowing the contamination of food stored in a company warehouse. The company experienced a mouse infestation problem resulting from the plowing of an adjoining farming field, and as Starr was in charge of handling sanitation problems, he took some corrective measures to fix the problem. In 1972, an FDA inspector inspected the company warehouse and discovered numerous violations of the Act, leading to count one of the information. The inspector communicated these violations to Mr. Cheney, the assistant treasurer, who then reprimanded the warehouse janitor and ordered him to take appropriate measures to correct the situation. The janitor failed to take these corrective steps and a second inspection one month later, leading to counts two and three of the

[46] 421 U.S. at 673.
[47] 421 U.S. at 673-675.
[48] *U.S. v. Starr*, 535 F.2d 512 (9^{th} Cir. 1976).

information, revealed that violative conditions still existed at the warehouse. Starr was convicted of all three counts against him and fined $200 for each.[49] On appeal, Starr argued that he should not be held responsible as to the first count because the mice infestation resulted from a "natural phenomenon"; the plowing of the adjacent field caused the mice to flee that sanctuary and infest the warehouse. To this argument the Ninth Circuit responded:

"... the duty of "foresight and vigilance"... requires the defendant to foresee and prepare for such an occurrence, whether it be deemed "natural" or "artificial." One with only a minimum of foresight would recognize that rodents and insects would flee from freshly plowed fields."[50]

As to the second and third counts, Starr argued that he should not be held responsible because the janitor sabotaged the company and refused to comply with the clean-up instructions given to him after the first inspection. The Ninth Circuit also rejected this argument, stating:

"The standard of "foresight and vigilance" encompasses a duty to anticipate and counteract the shortcomings of delegees... Once having notified [the janitor] of the need to correct the violations, Starr should have foreseen that, through neglect or design, [the janitor] might fail to follow the orders given by Cheney and himself. [The janitor's] actions or inaction were by no means wholly unforeseeable to Starr... Starr expected that [the janitor] would obey his orders, but this is not to say that noncompliance was unforeseeable, for indeed it was not."[51]

Another case decided the same year, *United States v. Y. Hata & Company*,[52] suggested that, in light of the strict "foresight and vigilance" test, the court would be reticent about allowing defendants to invoke an "objective impossibility" defense. In that case, FDA inspections revealed that there were

[49] 535 F.2d at 514.
[50] 535 F.2d at 515.
[51] 535 F.2d at 516.
[52] *U.S. v. Y. Hata & Co., Ltd.*, 535 F.2d 508 (9^{th} Cir. 1976), cert. denied, 429 U.S. 828 (1976).

birds flying in and out of a multi-food storage warehouse owned by Y. Hata & Co., and that there was bird excreta on some rice bags. A jury convicted the corporation and Minoru Hata, its president, on one count of the three-count indictment; he appealed arguing that he had been wrongfully denied a jury instruction on the defense of "objective impossibility".[53] Hata had been aware of the bird problem prior to the FDA inspection and had tried a number of methods to prevent the birds from entering the warehouse without success. At the time of the inspection, Hata was planning on erecting a wire cage around the food storage area to keep the birds out. Hata's argument for being entitled to an "objective impossibility" instruction was that: (1) before the inspection, it was not objectively possible for the corporation and himself to have thought of the wire cage system, and (2) at the time of the inspection, they could not construct the cage because the materials had not yet arrived.[54] To this argument, the Ninth Circuit responded:

"There was no proof or offer to prove that the wire cage system could not have been implemented long before the FDA inspections... Nor could there have been such proof or offer. A wire cage is scarcely a novel preventative device. One maintaining far less than the requisite "highest standard of foresight and vigilance" would have recognized [early on] that implementation of a wire cage system would substantially, if not completely, prevent access by thieving and untidy birds.... [T]he duty imposed by the Court in Park to "remedy violations when they occur" includes the duty to consider and experiment with a device so commonplace as a wire cage at a time long before that of the FDA inspections... Nowhere have the appellants offered to prove that they planned and attempted to install the wire cage system [early on]. Even had they done so, they would have had to offer proof that installation prior to the... inspections was frustrated by the inability to obtain materials from any source.... The trial record discloses

[53] 535 F.2d at 509.
[54] 535 F.2d at 511.

no evidence at all of the difficulty of obtaining materials... It is merely an assertion in the appellant's brief."[55]

The Ninth Circuit thus concluded that Hata was not entitled to an "objective impossibility" instruction and his conviction was affirmed.[56]

Four years later, in *United States v. New England Grocers Supply Co.*,[57] a Massachusetts District Court reiterated that liability could not be predicated on corporate title alone and provided more guidance as to the "objective impossibility" defense. In that case, New England Grocers Supply Co. (NEGSC), Julian Leavitt, president of NEGSC, Joel Leavitt, vice president of NEGSC, and Julian Schultz, vice president of NEGSC and general manager of the facility where the violations occurred, were all found guilty at a trial before a magistrate on each of the seven counts brought against them for violations of the Act. The corporation was fined $1000 on each count, Julian Leavitt was fined $250 on each of the seven counts, and Joel Leavitt and Julian Schultz were both fined $500 on each count.[58] The defendants appealed their convictions. The first ground of appeal, relating only to Julian Leavitt, was that the magistrate found Julian guilty solely because he was president of NEGSC at the time of the violations. The District Court pointed out that the decision in *Park* made it clear that "a finding of guilty cannot be predicated solely on the defendant's corporate position". The District Court thus concluded that the magistrate

[55] 535 F.2d at 511-512.
[56] 535 F.2d at 512.
[57] *U.S. v. New England Grocers Supply Co.*, 488 F.Supp. 230 (Mass. Dist. Ct. 1980).
[58] 488 F.Supp. at 232.

had incorrectly applied *Park's* "responsible relationship" requirement to Joel Leavitt as evidenced by the magistrate's statement that the "finding made by this court with respect to Julian was made only on the basis that in Park, the court stated that the position of the President made him liable, responsible and subject to prosecution."[59] The District Court remanded to the magistrate to determine whether the government had sustained its burden of proving beyond a reasonable doubt that Julian Leavitt bore a responsible relationship to the violations.[60]

The second ground of appeal was that the magistrate did not find beyond a reasonable doubt that the three individual defendants were not powerless to prevent or correct the violations under the Act. The District Court pointed out that, although the *Park* decision did not place a burden on corporate agents to do that which is objectively impossible, the decision did not make clear "the exact nature and scope of impossibility defense". The District Court then examined two possible interpretations of the impossibility defense. One interpretation was that the defense relates only to the corporate agent's power to correct or prevent violations by virtue of his corporate position.

"Under this interpretation, the evidence introduced by the defendant at trial to sustain his impossibility defense would serve only to rebut the evidence introduced by the government in establishing its prima facie case. Both sides would direct their proof to the responsible relationship vel non which the defendant bore to the violations of the Act."[61]

[59] 488 F.Supp. at 232.
[60] 488 F.Supp. at 234.
[61] 488 F.Supp. at 235.

Under this interpretation, the impossibility defense would not serve as an affirmative defense but rather would "merely provide corporate officers a defense open to all who are criminally accused... [,that is,] rebuttal of the government's proof".[62]

The other interpretation of the impossibility defense was that it is an affirmative defense requiring evidence that the corporate agent exercised "extraordinary care" yet was still unable to prevent the violation. The court pointed out many factors suggesting that this latter interpretation is the most appropriate[63], and concluded that the severe penalties associated with certain convictions under the Act warranted the adoption of the more lenient interpretation of the impossibility defense.[64]

As to the case at hand, the court reversed the findings of the magistrate with regard to the convictions of Joel Leavitt and Julian Schultz and remanded

[62] 488 F.Supp. at 235.

[63] "That this interpretation is what the Park Court intended is suggested by the Court's insistence that 'the Act, in its criminal aspect, does not require that which is objectively impossible.' This interpretation is also suggested by the Court's repeated emphasis that corporate officers must exercise the 'highest standard of foresight and vigilance' [citation omitted] and 'the highest standard of care'... The Park Court's citation to United States v. Wiesenfeld Warehouse Co. [citation omitted] is also illuminating.... Finally, further support for this second interpretation of the impossibility defense can also be found in the Court's suggestion that a corporate officer who introduces sufficient evidence of impossibility is entitled, upon request, to a jury instruction that the government is required to prove beyond a reasonable doubt that the defendant was not without the power or capacity to affect the conditions which founded the charges in the information [citation omitted]. This suggests a separate and distinct burden on the government to disprove an affirmative defense of impossibility, at least once sufficient evidence has been introduced by the defendant to raise that defense."
488 F.Supp. at 235-236.

[64] 488 F.Supp. at 236.

for a determination of whether they introduced sufficient evidence to raise the impossibility defense.[65] If so, the magistrate was then to decide whether the government was able to disprove the defense beyond a reasonable doubt. As to Julian Leavitt, if the magistrate determined on remand that he bore a responsible relationship to the violations, then the magistrate was also instructed to determine whether he succeeded on his impossibility defense.[66] The court summarized its position on the impossibility defense stating the following:

"

In sum, the impossibility defense allows the corporate officer to introduce evidence to establish an affirmative defense that he exercised extraordinary care and still could not prevent violations of the Act. The defense is raised when the defendant introduces a sufficient quantum of evidence as to his exercise of "extraordinary care" so as to justify placing an additional burden on the government. At this point, the government must prove beyond a reasonable doubt that the defendant, by the use of extraordinary care, was not without the power or capacity to correct or prevent the violations of the Act.... Of course, the corporate officer may always introduce evidence that by reason of his corporate position he did not have the power to prevent or correct violations of the Act, and thereby rebut the government's proof of his "responsible relationship" with the violations."[67]

[65]Note that there is no other published decision involving the *New England Grocers Supply Co.* parties.
[66]488 F.Supp. at 236-237.
[67]488 F.Supp. at 236.

Part IV

Defenses to Criminal Charges for Violations of the Act

There are two main types of defense available to defendants who have allegedly violated provisions of the Act: an impossibility defense and a constitutional defense.

The impossibility defense was discussed at length in the *New England Grocer Supply Company* case above, and thus needs no further elaboration. Essentially, if a corporate agent charged with a violation under the Act can prove that he or she was powerless to correct the violation, then the burden shifts to the government to prove that the agent was not, in fact, unable to correct the violation.

As to a constitutional defense, alleged violators have attacked the constitutionality of the Act's enforcement provisions under both the Fourth or Fifth Amendments. In a 1998, American Criminal Law Review Article,[68] Erica Niezgoda and Maureen Richardson summarized the current status of these defenses. With respect to Fourth Amendment challenges focusing on the legality of administrative searches conducted by FDA inspectors, they pointed to cases suggesting that, although the general rule is that the Fourth Amendment applies to administrative inspections of commercial property, "legislative schemes which

[68]Erica L. Neizgoda and Maureen M. Richardson, *Federal Food and Drug Act Violations*, 35 Am. Crim. L. Rev. 767 (1998).

authorize warrantless administrative searches of commercial property do not necessarily violate the Fourth Amendment where the warrantless inspection involves a closely regulated industry." Furthermore, warrantless inspections are reasonable if: "(1) a substantial government interest... informs the regulatory scheme pursuant to which the inspection is made, (2) the inspection is necessary to further [the] regulatory scheme, and (3) the statute's inspection program both in terms of certainty and regularity of its application provides a constitutionally adequate substitute for a warrant."[69] As to whether valid consent is necessary to legitimize a warrantless search, the authors note that authorities are divided but that even in jurisdictions requiring consent and thus requiring the FDA to obtain a search warrant before entering the premises, such a warrant "requires a more relaxed demonstration of evidence than that required by traditional Fourth Amendment standards."[70] Thus sustainable Fourth Amendment challenges are rarely presented, unless the FDA subjects the defendant's home or car to a search[71] (which is not the usual course of events).

With respect to Fifth Amendment due process challenges**,** which are generally based on the vagueness of a particular provision or lack of notice, Niezgoda and Richardson indicate that defendants have not yet been successful. On the other hand, corporate agents do have the right to invoke the Fifth Amendment privilege against self-incrimination under certain circumstances. *Miranda* warnings are not required, however, prior to interviews with FDA inspectors

[69] *Id.* at 775.
[70] *Id.* at 776.
[71] John W. Lundquist and Sandra L. Conroy, *Defending Against Food and Drug Prosecution*, 21-JUL Champion 21, 21 (July 1997).

because "courts have consistently found that company representatives on their own premises are neither in custody nor deprived of their freedom since they are not prohibited from moving about the premises nor prohibited from consulting their attorneys during the FDA inspections."[72]

Thus it would seem that corporate agents seeking to defend their actions can rely only on an impossibility defense, however it should be noted that this defense places a large burden, often seemingly insurmountable, on the corporate defendant.

Part V

Pros and Cons of Strict Criminal Liability for Violations of the Act

During Daniel O'Keefe Jr.'s tenure as President of the Food and Drug Law Institute, he co-wrote an article discussing, among other things, the pros and cons of personal criminal liability under the Act.[73] He identified the following arguments in favor of imposing strict criminal liability upon individuals who violate provisions of the Act:[74]

(1) Strict criminal liability best protects public welfare in "providing the

[72] *Id.* at 778.
[73] Daniel F. O'Keefe Jr. and Marc H. Shapiro, *Personal Criminal Liability Under the Federal Food, Drug and Cosmetic Act - The Dotterweich Doctrine*, 30 Food Drug Cosm. L.J. 5 (Jan. 1975).
[74] *Id.* at 38-39.

best possible deterrent to violations of the Act by motivating businessmen to seek to attain the highest possible standard of care by taking affirmative action and by instituting necessary safe and sound practices to assure that violations do not occur, lest they be branded criminals and risk imprisonment."

(2) Strict criminal liability makes the law "self-executing" thus reducing the amount of enforcement staff necessary to oversee large amounts of commodities.

(3) Strict criminal liability discourages legal "brinksmanship" (such discouragement being a benefit which he describes as encouraging businesses to err on the side of protecting the public).

(4) Other methods of enforcement such as civil penalties can be viewed merely as a cost of doing business thus making them less effective in protecting public welfare.

(5) Strict criminal liability has not been abused by the government and, even if it were to be, the courts could prevent such abuse from going forward.

(6) Proof of knowledge or willfulness would often be difficult to prove, and requiring such proof would defeat the primary purpose of the Act which is to protect public welfare.

Of this list of theoretical arguments in favor of the imposition of personal criminal liability, it seems that the most often cited argument is the deterrence rationale.[75] There is no evidence, however, that personal criminal liability is an

[75]Note that the argument that civil penalties would not be as effective because they could be viewed simply as a cost of doing business is also often referred to. This argument is not really separable from the deterrence argument, however, insofar as it suggests that only the imposition of criminal penalties will be an adequate deterrent.

effective deterrent in the context of corporate law violations.[76]

O'Keefe also pointed to the following arguments that are advanced against strict criminal liability under the Act:[77]

(1) Strict criminal liability is "unjust" and other enforcement mechanisms could be used which would be as effective in protecting the public welfare. Other statutes that deal with the health and safety of the public are enforced without using strict liability and there is no evidence that businessmen fail to observe these statutes any more than provisions of the Act.

(2) Other enforcement tools may be more effective than strict criminal liability because courts and juries are hesitant to make criminal convictions unless there is evidence of wrongdoing.

(3) It is unfair to subject people to potential prosecutions where the requirements of the Act are not clear (as is often the case), where violations do not affect health or safety, where a second conviction results in a felony charge, or where the individual faces imprisonment.

(4) The deterrence rationale of strict criminal liability does not apply if the alleged offender did exercise reasonable care and was unaware of a violation.

[76]S. Prakash Sethi and Robert W. Katz, *The Expanding Scope of Personal Criminal Liability of Corporate Executives - Some Implications of United States v. Park*, 32 Food Drug Cosm. L.J. 544 (Dec. 1977). Sethi and Katz note that no systematic studies have been performed to measure the deterrent effect and any analogies of such an effect can only be inferred from criminal law where the relationship between incarceration and crime prevention is not clear. Furthermore, they suggest that any potential deterrent effect would be weakened if the alleged corporate offender's peer group did not view that offender's actions as criminal. *Id.* at 546.

[77]O'Keefe and Shapiro, *supra* at 39-40.

(5) The government might use the threat of criminal prosecution to demand additional behavior on the part of a company that is not required by law.
(6) Branding individuals who were unaware of their wrongdoing as criminals can weaken the stigma associated with criminal convictions and thus compromise the integrity of the criminal justice system by weakening its deterrent effect.[78]

Another argument against the imposition of strict personal criminal liability in the context of food and drug law violations is that, assuming risk aversion on the part of corporate executives, it can lead to a socially sub-optimal outcome. If corporate executives are fearful of the imposition of, or even threat of, criminal penalties, they may make overly cautious decisions thus compromising corporate efficiency. One could argue that this cautious behavior is in fact a benefit (as does O'Keefe's in his legal brinksmanship argument) but there is a point at which the benefits of such behavior do not outweigh the benefits of improved

[78]In his article on public welfare offenses, Sayre also made this argument.
"The moral obloquy and the social disgrace incident to criminal conviction are whips which lend effective power to the administration of criminal law. When the law begins to permit convictions for serious offenses of men who are morally innocent and free from fault, who may even be respected and useful members of the community, its restraining power becomes undermined. Once it becomes respectable to be convicted, the vitality of the criminal law has been sapped. It is no answer that judges convinced of the actual moral innocence of the defendant, may impose only a nominal punishment. The harm is wrought through the conviction itself and through the subjection of innocent men to the possibility of having imposed upon them by some ignorant or prejudiced judge the substantial punishment which the crime allows."
Sayre, *supra* at 79-80.
It should also be mentioned that until the stigma associated with criminal indictments and convictions is weakened, defendants in criminal cases under the Act, whether or not they are ultimately convicted, will suffer stigmatization and other personal ramifications. According to one article, one such defendant informed his lawyer that during the four years between his indictment and ultimate acquittal, he did not participate in any social engagements. In an effort to highlight the import of that statement, the author asked the reader to consider how many social engagements they had attended during the past four years. George M. Burditt, *The Park Case in Perspective*, 31 Food Drug Cosm. L.J. 139 (Mar. 1976).

corporate efficiency, and such behavior may have a net negative effect on social welfare.

Part VI

Criminal Prosecutions Under the Act

As described above (in Part V), there are potential benefits to the imposition of strict criminal liability for violations under the Act, but there are also serious drawbacks to such an imposition. These drawbacks are only of concern, however, if the FDA is, in fact, imposing strict criminal liability on corporate agents.

Under the Act, the FDA can choose to afford a Section 305 hearing to an alleged violator of the Act at which time such person can respond to the allegations and attempt to dissuade the FDA from recommending prosecution. However, such hearings are not required and currently, according to Peter Barton Hutt, the FDA seldom grants such hearings. The Department of Justice can also refuse to prosecute, although it tends to follow the recommendations of the FDA. Prosecution is more likely if the alleged offender "was previously notified of suspected violations and thereafter refused to correct the offending conduct... [,or] if the violation was intentional, easily detectable, preventable, fraudulent, or life threatening."[79] There are, however, no formal criteria defin-

[79]Lundquist & Conroy, *supra* at 21.

ing who qualifies as a "responsible person", or particular circumstances under which an individual will not be prosecuted. Thus, strict criminal liability is a real threat to corporate agents.

In 1991, Dr. David Kessler, the FDA commissioner, stated that he wanted to restore the "credibility and integrity" of the FDA and "the only way to do that [was] to focus on strong enforcement."[80] According to an article from that same year, the percentage of FDA recommendations to the Department of Justice for criminal prosecution was higher in the previous two fiscal years than ever before.[81] Furthermore, between 1993 and 1995, the number of arrests went from 58 to 146, while the number of convictions went from 10 to 106.[82]

Part VII

Is Strict Personal Criminal Liability Necessary to Achieve its Desired Goals?

It is clear that corporate agents in the food and drug industry currently face a risk of prosecution under a strict personal criminal liability standard for violations of the Act.[83] Thus, it is important to ask: (1) what the goals of using the

[80]Herbert Burkholz, "FDA Reform Spurred by One Man's Drastic Prescription", L.A. Daily News June 30, 1991 - VPT1.

[81]Kowal, *supra* at 274.

[82]Lundquist and Conroy, *supra* at 21.

[83]The Department of Health, Education and Welfare stated in *S.Rep.* 684, *94th Cong.,*

strict liability standard are, and (2) whether use of this standard is necessary to achieve those goals.

One goal of imposing strict liability is to accommodate the fact that there are relatively few FDA inspectors as compared to the number of establishments producing and distributing FDA regulated goods (including companies handling food, medical device firms, companies handling drugs for human use, and firms making and selling animal drugs and medical feed). It is argued that strict liability provides an impetus to self-regulation insofar as it creates fear that "criminal penalties may be imposed for failure to take every precaution to insure that violations - and their potentially harmful consequences - will not occur." Furthermore, "without the presence of a strict liability standard cost conscious executives will be tempted to lessen their efforts toward insuring compliance and instead wait to be cited for a violation and then undertake corrective action."[84]

2^{nd} *sess.* (1976) that "the law, properly construed, [does not] permit imposition of criminal penalties on an executive officer for the acts or omissions of others. It is the officer's personal neglect that is punishable." In the very same report, however, the Department argues against a change that "would weaken the standard of strict criminal liability for a violation of the act," and claims that "strict criminal liability is an indispensable adjunct to the Food and Drug Administration's efforts to enforce the act." The Department thus admits that the Act imposes strict criminal liability on food and drug industry participants. Furthermore, it is not reasonable to argue that officers' "personal neglect" is being punished in all cases holding officers liable for the acts or omissions of others. Given the size and geographic dispersion of many food and drug corporations, executive officers can exert best efforts (measured by an objective standard) to monitor all happenings within the corporation and yet fail to catch some violations before they occur. The occurrence of these violations cannot properly be attributed to the officers' neglect but are rather the result of the purposeful, reckless, or negligent acts of another, and to hold the officers responsible for these violations cannot be described as anything but the application of strict liability.

[84] *Id.*

It goes without saying that enforcement of laws or regulations with few resources is difficult. It does not follow, however, that the application of strict liability is the only, or best, way to achieve compliance. It is not necessarily the case that without strict liability, corporate agents or executives will take less care or only take corrective actions after violations are discovered. For example, the existence of a corporate compliance program defense (discussed below) only allows executives to escape liability if appropriate precautionary action is taken prior to the discovery of a violation. And, the use of civil monetary penalties (discussed below) set at a level to achieve the same deterrent effect as strict liability, or the use of a negligence standard (discussed below) with due care levels set to achieve the same deterrent effect, will induce executives to behave in the same manner as under a strict liability standard. Thus, strict liability is not necessary to accommodate a lack of FDA resources.

Another goal of imposing strict liability is to achieve optimal safety in the food and drug industry. The legislative history and judicial dicta discussed above (see Parts II and III) indicate that the most cited justifications for use of a strict liability standard are based on notions of deterrence and protection of the public welfare. Implicit in these justifications is the idea that the drafters of the Act and the judiciary are seeking to achieve a socially optimal level of activity in the food and drug industry and a socially optimal level of safety. Note that it is highly unlikely that their aim is to eliminate violations of the Act altogether, thus it should not be surprising that violations and resultant

convictions occur.[85] Whether the number of violations is at the socially optimal level is another issue, however. It could be the case that the imposition of criminal sanctions for violations under the Act by those corporate agents standing in responsible relationship to the violations, yet unaware of the perpetration of the violations, is too severe thus over-deterring participation in the industry (or causing suboptimal levels of precaution-taking efforts). Even if the imposition of such criminal sanctions is the optimal enforcement technique, it could be the case that corporate agents are personally risk averse thus causing them to participate in the industry less than the socially desirable level (or to become overly precautionary). Conversely, it could be the case that the criminal sanctions currently imposed are too lenient resulting in too much participation in the industry (or not enough precautionary efforts).

Unfortunately, it is impossible to know whether the current level of participation in the industry, the current levels of precautionary care and the current level of criminal convictions are at the socially optimal level. Thus it is unclear whether changes in the liability standard or level of criminal sanctions yielding an increase or decrease in convictions would signal an improvement over the current situation. Assuming, however, that the current levels of participation and safety are at the social optimum, and given the serious repercussions of personal criminal liability (as discussed above in Part VI), it is worth determining whether the enforcement mechanism of the Act could be changed to achieve the same, or better, industry participation and levels of safety without some of the

[85] If the aim was to eliminate violations altogether, one would expect the use of harsher penalties, and such a goal would necessarily come at the expense of stifling socially desirable participation in the industry (a consequence that is not a rational desire).

drawbacks associated with the current scheme.

1.

Corporate Compliance Program Defense

An internal compliance program is aimed at reducing the risk of violations under the Act by educating corporate employees and agents such that they can more readily avoid inadvertent acts, and by deterring potentially intentional acts through the threat of disciplinary action.[86] Currently, under the Federal Sentencing Guidelines for Organizations, the existence of an "effective" internal compliance program can reduce corporate fines by up to eighty percent (so long as management officials did not participate in, condone or avoid knowledge of violative conduct).[87] The minimum requirements for a compliance program to be considered "effective" were summarized by Kowal as follows:[88]

(1) The establishment of compliance standards and procedures that are reasonably capable of reducing the prospect of criminal conduct.

(2) The assignment of compliance oversight to specific high level personnel.

[86] "The most effective compliance program will inform management and employees of the standard of legal and ethical conduct that is required by the company and industry, and create a series of incentives for compliance with that standard. The program will send a strong message to employees that compliance with laws and regulations is required and that deviation from that standard will not be tolerated by the company. In essence, the program will help to foster a corporate culture of concern for and obedience to the law. The generation and maintenance of such a corporate climate likely will prevent many potential violations."
Steven M. Kowal, *Corporate Compliance Programs: A Shield Against Criminal Liability*, 53 Food & Drug L. J. 517, 519 (1998).

[87] *Id.* at 519, 525.

[88] *Id.* at 523-524.

(3) The exercise of due care not to delegate discretionary authority to agents who have, or should have been known to have, "a propensity to engage in illegal conduct".

(4) The effective communication of standards and procedures to all employees and agents of the corporation.

(5) Compliance with these standards by ensuring that reasonable steps are taken to remain in compliance.

(6) The consistent enforcement of standards "through appropriate disciplinary mechanisms."

(7) Taking reasonable steps, after the detection of an offense, to "respond appropriately... to prevent future offenses."

(8) Program tailoring to address "the particular issues and problems inherent in each company", and to ensure that the program is "reasonably capable" of preventing and detecting potential violations (i.e., there must be adequate employee training and proper documentation of procedures, and the program should "ensure that all manufacturing procedures are followed, that all necessary approvals are obtained, and that changes in product design or production are not made without appropriate agency review").

The implementation and existence of an internal compliance program "provides a strong basis to persuade the government that the company (and perhaps its senior executives) should not be charged for the criminal conduct of lower level employees" because there is little to be gained from a deterrence perspec-

tive by imposing criminal charges when "reasonable steps already have been taken to prevent improper activity".[89] Currently, however, the existence of an effective program, although it can reduce corporate fines, does not provide an absolute defense to corporate employees or agents who did not know, and could not have been expected to know, about violative conduct committed by other employees or agents.

It makes sense that if allowing an absolute defense in this context would not negatively affect the deterrence function of the current enforcement mechanism, and thus would presumably not cause a decline in the level of safety, the defense should be permitted. If the defense was allowed and properly recognized by the courts, corporate agents would not be suboptimally discouraged from participating in the industry due to the fact that they would no longer fear that the wholly independent actions of other employees could result in criminal liability being imposed on them. Of course, any person who wilfully engaged in violative conduct in contravention of the compliance program could be subject to the current criminal sanctions, and agents of a corporation that did not have an effective compliance program in place could also be treated in the same fashion as is currently the case. Imposing criminal sanctions in these contexts, however, would be consistent with the notion that criminal penalties should only be used when the alleged offender exhibited some form of knowledge or intent to commit

[89] *Id.* at 519.

the violation.[90]

If the defense was allowed in the criminal context, a separate issue would be whether victims could bring civil actions against corporate agents who had invoked the defense in response to criminal charges. Whereas the primary function of criminal liability is to deter misconduct on the part of the individual defendant and all similarly situated persons, civil liability also serves to compensate victims for the harms they suffer as a result of the defendant's conduct. Thus allowing the compliance program defense in the context of civil suits would have the arguably negative effect of forcing victims to bear the burden of violative conduct (unless there was at least one person who was not judgment-proof, and who acted wilfully in causing the violations to occur in which case the defense would not apply). Of course, if the civil action is a shareholder derivative suit, there is probably less concern about ensuring "victim" compensation.

Under a regime where corporate agents could use the implementation of an "effective" compliance program as a defense to vicarious liability for the violative conduct of other employees or agents, there would likely be an increase in

[90]As to agents of a corporation that does not have an effective compliance program in place and in which a violation occurs, one could argue that the agents lack sufficient intent to be held liable (especially if they have no control over corporate policies and procedures). However, agents without control to implement an effective compliance program could have always chosen not to work for a corporation that was lax in that area and their decision to stay could be viewed as a form of knowledge. As to agents who do have control, they could be seen as having an intent to commit the violation insofar as they took no steps to create an effective program to guard against its occurrence.

the number of such programs instituted in the food and drug industry.[91] This would be true so long as the costs of implementing compliance programs did not exceed the benefits of such implementation.[92] Furthermore, the structure of an "effective" compliance program could be adjusted to achieve the socially desirable level of industry safety (whatever level that may be) taking into account the fact that increased safety generally translates into less innovation and participation in the industry.

B. *Civil Penalties Rather Than Criminal Sanctions*

It has been argued that criminal sanctions for individual corporate agents are necessary because civil monetary penalties alone might be seen as merely a cost of doing business and thus presumably not result in an appropriate level of safety in the food and drug industry.[93] This argument is premised on two

[91] One might argue that the *Park* decision should also encourage an increase in effective compliance programs because the presence of such programs would presumably reduce the likelihood of violative conduct and thus the likelihood that corporate agents would face criminal liability. This could be true, although the fact that, under *Park*, corporate agents can still be held vicariously liable for violations of the Act despite the existence of such programs enormously decreases the expected benefits of such programs from the perspective of the corporate agents. Thus, depending on the costs of such programs, individual corporate incentives to implement them may fall short of making the implementation of such programs seem worthwhile.

[92] It is highly unlikely that individual corporations would not find implementation of internal compliance programs to be cost effective. Individual corporate agents would receive substantial personal benefits in the form of not worrying about the various repercussions of criminal charges they could face as a result of the conduct of others. Furthermore, the existence of the compliance defense would enable the corporate entity to avoid large corporate fines. There is also a potential social benefit to increased implementation of compliance programs: if the existence of an effective compliance program is easy to detect, some cases that currently result in extensive litigation would either not be brought or could be summarily decided thus reducing enforcement costs. Of course, if determining whether a compliance program is "effective" would result in the same amount of litigation or investigative resources, then this proposition does not hold. If it does hold, however, then the government could provide incentives for implementing compliance programs should the individual corporate incentives prove not to be great enough.

[93] For example, Eric Blumberg, deputy chief counsel for litigation at FDA, stated that the naming of individuals in criminal actions is to ensure that corporations do not view fines and penalties as a cost of doing business. *FDA Enforcement Will Rely on More Criminal Actions,*

related assumptions that should be more fully explored before accepting the idea that civil monetary penalties would not be adequate: (1) corporate executives, separate from the corporate entity, are only deterred by the threat of criminal sanctions as opposed to civil monetary penalties, and (2) civil monetary penalties cannot provide an equal level of deterrence as criminal sanctions.

As to the first assumption, it is highly speculative to presume that individual corporate employees or agents would not take the threat of personal monetary liability seriously in contemplating their actions. Assuming no reimbursement from the corporation, a corporate agent does not often have the resources available to him or her as does the corporation and is thus not likely to view monetary penalties as simply a cost of doing his job. This is especially true insofar as the corporate agent does not always directly benefit from reduced levels of safety in the same manner as the corporation can. Of course, there is always the worry that a corporate agent will be able to hide, or otherwise protect, his assets such that he will be judgment-proof in the face of monetary liability. For this reason it may be thought that criminal sanctions along with their associated social repercussions are necessary to achieve appropriate deterrence, but the problem might instead be adequately addressed in the majority of instances by laws such as those invalidating fraudulent transfers. There is also the concern that corporations would pay the fines by reimbursing the corporate agents or raising their salaries, but this practice could simply be prohibited and such prohibition

Says Michels 7/4/94 Food Chemical News (page unavailable).

enforced.[94]

As to the second assumption, economic principles suggest that civil monetary penalties could be set to result in the same level of deterrence as is achieved through the imposition of criminal sanctions. Civil monetary penalties set at the same level as criminal fines might not provide the same level of deterrence due to the fact that the criminal fines have associated repercussions (i.e., social stigma) that make them more effective from a deterrence perspective, but this can be compensated for by simply setting the civil penalties at a higher level than the criminal fines. Of course, if the required level of civil penalties is so high as to render defendants judgment-proof, then criminal sanctions might be necessary. Before civil monetary penalties are rejected as a replacement enforcement tool, however, it should be determined how high they would have to be set to result in the current level of deterrence and whether most corporate defendants would be able to afford those penalties.

If civil monetary penalties could be used to achieve the same level of deterrence as criminal sanctions under the current strict liability standard, they would be preferable insofar as they are not burdened by many of the same problems dis-

[94]The prohibition could be enforced by (1) disallowing any payments to the offending corporate agent for a specified period of time (aside from the corporate agent's salary at the time the suit was filed or the corporation was notified of the intent to file suit), and (2) shutting down, or if applicable refusing to give FDA approval to, any corporation making such payments. A corporation making such payments would have to record them (even if such payments were made in kind) in the company's books for tax purposes and could thus be monitored through audits. Presumably, the threat of effectively losing the corporation would remove any temptation to reimburse corporate agents. Note also that any "under the table" payments are already prohibited by the IRS, and could be monitored by the IRS in the same fashion that "under the table" payments are monitored in other contexts.

cussed in Part V that are associated with the imposition of criminal penalties for unintentional violations under the Act.[95]

One issue that would need to be addressed if criminal sanctions were replaced with civil monetary penalties (and all forms of corporate reimbursement were prohibited) would be whether corporate employees and agents could be insured against such penalties. The enforcement of liability insurance for intentional wrongdoing is generally precluded on public policy grounds (i.e., insurance would encourage the socially undesirable conduct constituting the wrongdoing, or in other words, reduce the deterrent effect of liability).[96] Some courts have allowed an exception to this general rule for liability that is imputed to employers as a result of intentional torts committed by their employees on the basis that the insurance is not covering the insured's intentional wrongdoing but rather someone else's.[97] Courts have also recognized an exception allowing employers to insure against liability incurred for the negligent supervision of their employees.[98] Both exceptions are consistent with the public policy grounds upon which liability insurance is prohibited for intentional wrongdoings (i.e., the exceptions would not seem to promote intentional wrongdoings). The negligent supervi-

[95] Criminal sanctions can remain in place for wilful or knowing violations of the Act because there is an "intent" requirement associated with them and they are thus less objectionable. It should be noted, however, that civil penalties could theoretically be appropriately set to achieve adequate deterrence in the context of wilful violations as well(unless these violations tend to be committed by lower-level employees who would likely be judgment-proof against such penalties).

[96] Sean W. Gallagher, *The Public Policy Exclusion and Insurance for Intentional Employment Discrimination*, 92 Mich. L. Rev. 1256, 1267 (Mar. 1994).

[97] *Id.* at 1276.

[98] *Id.* at 1281.

sion exception, however, does potentially create an incentive for employees to behave negligently in their supervisory tasks. In the food and drug industry, if civil monetary penalties are set to achieve socially optimal levels of safety, liability insurance that might encourage negligent supervision of employees could result in suboptimal overall safety levels. This would suggest that insurance should not be enforced in those circumstances. In the case of non-negligent employers or employees in supervisory positions, however, coverage should be enforced when liability is imputed for the wrongful acts of subordinates. Insurance in this context will not reduce the deterrent effect of civil liability and it will allow particularly risk averse agents to behave in a more socially optimal manner.[99]

3.

Negligence Standard

1.

Another option for change would be to move from a strict liability standard for adjudicating claims of violations under the Act to a negligence standard.[100]

[99] If civil penalties are set to ensure the socially optimal level of participation in the industry, taking into account regular levels of risk aversion, those corporate agents who are particularly risk averse will not participate at the socially desirable level. The availability of insurance, however, can counter that risk aversion and result in more optimal participation.

[100] Some have argued that the *Park* standard is already a negligence standard, but the *Park* standard allows criminal liability to attach in tenuous situations wherein it is difficult to identify "wrongful" conduct on the part of the corporate agent. The acts of the corporate agent are not compared to those of an average reasonable man, but are rather judged assuming incredible foresight on the part of the agent (as evidenced by the Ninth Circuit's requirement in *Starr* that the defendant foresee and prepare for fleeing rodents and sabotage on the part of his employee). This is not in line with traditional notions of a negligence standard.

In 1948, the Senate passed an amendment to the Act[101], which was subsequently stricken,[102] requiring that violations be committed "willfully or as a result of gross negligence" in order to impose criminal liability. In 1976, the Senate passed the Consumer Food Act which amended section 303(a) of the Act to require that the imposition of criminal penalties depend upon whether the individual "knowingly, or wilfully, or negligently violated, or caused the violation of," the Act.[103] The House, however, subsequently struck the Consumer Food Act. In 1979, the Senate passed, but the House failed to consider, the Drug Regulation Reform Act which amended section 303(a) and (b) of the Act by adding the word "negligently" before the word "violates".[104] It now might be time to again reconsider a move to a negligence standard.

One of the complaints about the strict liability standard is the perceived "unfairness" of imposing criminal liability on persons who lack intent to engage in, or even lack knowledge of, the commission of a violation.[105] Use of a negligence

Furthermore, in *S. Rep* 321, *96th Cong., 1st sess.* (1979), it is stated that "under the current law, as interpreted by the *Park* decision, a person who commits a prohibited act is subject to criminal penalties regardless of the person's knowledge or intent," and that the revised penalty section of the bill in question "would overrule the *Park* strict liability doctrine, and it would substitute a negligence standard." [emphasis added.] This report suggests an admission that the *Park* standard is not a negligence standard.

[101] 94 Cong. Rec. 6760-6761 (1941).

[102] 94 Cong. Rec. 8551, 8838 (1941).

[103] *S. Rep.* 684, *supra.*

[104] *S. Rep.* 321, *supra.*

[105] Although courts apply the *Park* Court's "foresight and vigilance" test in determining whether to hold a corporate defendant liable, findings under this test suggest that courts will conclude that the test has been satisfied regardless of how fair it is to assume that a reasonable person would have foreseen the commission of the violation in question. *See*, e.g., *U.S. v. Park*, 421 U.S. 658 (1975)(president of large corporation based in Philadelphia who was responsible for overseeing operations in a number of warehouses and outlets was held responsible for violations occurring in a Baltimore warehouse); *U.S. v. Starr,* 535 F.2d 512 (9th Cir. 1976)(court found that foresight and vigilance standard required corporate agent to anticipate, among other things, that delegees would not follow orders); *U.S. v. Y. Hata &*

standard, along with the traditional requirements of actual and proximate causation, would eliminate this complaint. Of course, under a negligence standard, criminal convictions could still ensue without "intent" to commit a violation or actual "knowledge" that a violation was being committed as required under willful conduct or recklessness standards. Use of a negligence standard, however, would at least imply that there was some "wrongfulness" attributable to the defendant's conduct.[106] Ensuring that corporate agents only faced criminal sanctions after having been found to have committed a wrong of sorts would also address the concern that criminal sanctions should not be imposed in the absence of wrongdoing lest the criminal justice system lose its legitimacy.

It should be noted that the strict liability standard can be replaced with a negligence standard without sacrificing the deterrent effect of enforcement, so long as the "due care" level of precautionary conduct (above which corporate defendants will not face liability) is set at the appropriate level. A simple example will demonstrate this proposition: Imagine that a senior corporate employee in a potato chip manufacturing plant can choose between exercising level 0, 1,

Co., Ltd., 535 F.2d 508 (9^{th} Cir. 1976) (court found that foresight and vigilance standard required corporate agent to foresee that a wire cage system would be necessary to keep birds out of warehouse instead of other methods used unsuccessfully by the agent).

[106]Note that typically a criminal negligence standard allows for a "far greater latitude of permissible behavior on the part of the defendant before liability attaches than is allowed in civil cases" and it is sometimes necessary for the government to prove that the defendant acted "recklessly" or "wantonly". *S. Rep.* 684, *supra.* A civil negligence standard, in comparison, requires a defendant to meet the "due care" standard which allows liability to attach for conduct that is not necessarily reckless or wanton. Thus, it would be important to ensure that any amendment to the Act substituting a negligence standard for the current strict liability standard made it clear that courts should instruct juries under a standard of negligence ordinarily used in civil actions rather than criminal actions.

2, 3 or 4 of care (i.e., at level 0, the employee does not supervise any of his subordinates and ignores visible signs of chip contamination whereas at level 4, the agent keeps close watch over every subordinate and manufacturing process). The cost of care at each level is $0, $150, $250, $350, and $600 respectively (taking into account the time and effort involved in increased precautions, lack of innovation, and decreased production). At every level of safety there is an associated risk of contamination which decreases as the level of safety increases. The following hypothetical chart illustrates the expected total harm from contamination at each level of care assuming that contamination results in a harm of $1000.[107]

Level of Care	*Cost of Care*	*Risk of Contamination Harm*	*Expected Harm From Contamination*	*Total Expected Costs (cost of care + expected harm)*
0	0	95%	950	950
1	150	85%	850	1000
2	250	70%	700	950
3	350	50%	500	850
4	600	30%	300	900

In this example, the socially optimal level of precautionary care to be taken is "3.[108] Assuming that criminal sanctions are proportional to the expected

[107]Of course it is assumed that the benefits of having a potato chip manufacturing plant exceed the total expected costs of the plant such that having the plant in the first place is socially desirable and the only issue is how to encourage corporations to take the socially optimal level of precautionary care.

[108]One might posit that the socially optimal level of precautionary care to be taken is "4 because that level results in the lowest expected harm from contamination. This position fails to take into account the costs associated with achieving that level of care, however, and thus suggests that the optimal level of care is not the level at which there are the least expected

harm from contamination at each level, then the employee in a strict liability regime will take the socially desirable level of care because he will bear the sanctions regardless of the level of care taken and will thus take the level of care that minimizes his total expected costs.[109] Under a negligence regime, the employee will also take the socially desirable level of care[110] so long as the "due care" standard is set at that level.[111] Of course, if the court does not use the correct due care standard, then the employee can be encouraged to take a suboptimal level of care.[112]

Thus, one drawback of the negligence standard is that effective deterrence depends on the court properly setting the due care standard. Furthermore, due care standards tend not to incorporate all behavioral factors whereas a strict liability standard forces an employee to implicitly take all factors into consid-

total costs - a position at odds with the economic concept of social optimality. If the socially optimal outcome was defined as that which resulted in the lowest harm to society irrespective of the cost to achieve that level of harm, then the argument that level "4 is optimal would hold. However, this definition of the socially optimal outcome is rather nonsensical insofar as the costs incurred to achieve the desired level of harm are themselves a "harm" as they represent a diversion of resources, a decrease in efficiency, lack of innovation, delays in the introduction of new products, etc.

[109]Note that not all costs of care are borne directly by the employee, but rather some are borne by the corporation. Thus the employee will act, not based on the total expected costs at each level of care, but rather on the expected cost at each level that takes into account expected sanctions (reflected by expected harm from contamination) and only those costs of precautionary care that he bears himself. Depending on the cost of care not borne by the employee, this situation can lead the employee to take excessive care assuming that the expected sanctions are lower at higher levels of care. Although this is suboptimal behavior, it is at least in the direction of taking too much, rather than too little, care.

[110]The same caveat discussed in footnote 109 applies under the negligence standard as well.

[111]If the due care standard is set at level "3, the employee can take either level 3 care at a cost of $350 or level 4 care at a cost of $600 and face no criminal sanctions, or he can take care at lesser levels and face the corresponding sanctions in addition to the cost of care. His total expected costs will thus be less at level 3 or 4 care, and since he has no financial incentive to take more care than the due care standard, he will take the socially desirable level of care.

[112]For example, if the court holds employees to a higher than optimal level of care standard (i.e., level 4), then the employee will take that level of care at a cost of $600 rather than face the cost of care and expected sanctions at the lower level of care. Conversely, if the court holds employees to a less than optimal level of care standard, such as level 2, then the employee will have no incentive to take any more than level 2 care.

eration. For example, level of activity is one factor that is assumed not to be considered by courts in determining the due care standard.[113] To illustrate the effect of this omission, imagine the corporate employee from the example above can run the plant for a quarter day, half day, three-quarter day or full day. The following hypothetical chart illustrates the increased cost of care and benefits at each level of production (assuming that the socially desirable level of care is employed).

Level of Production	*Cost of Care*	*Expected Harm From Contamination*	*Expected Benefits*	*Total Expected Social Welfare*
1/4 day	350	500	1000	150
1/2 day	700	1000	2500	800
3/4 day	1050	1500	3500	950
full day	1400	2000	4200	800

The socially desirable level of production is running the plant for a three-quarter day.[114] Again assuming that criminal sanctions are proportional to the expected harm from contamination, an employee in a strict liability regime will engage in the socially desirable level of production because he will reap the benefits and experience all of the costs and sanctions at each level of production such that his welfare mirrors the social welfare. On the other hand, an employee

[113]Steven Shavell posits that courts do not include level of activity in the determination of negligence because courts would have to determine the benefits derived by parties from their activities. Since these benefits cannot be accurately assessed, "attempts by courts to determine appropriate levels of activity would probably quickly land them in the most speculative of realms." Furthermore, courts would have to determine the parties' actual activity levels which could be difficult. Steven Shavell, Principles of Economic Analysis of Law Ch. 13: 19-20 (forthcoming).

[114]This is because, from a social perspective, the expected benefits exceed the sum of the cost of care and expected harm from contamination by the widest margin at the three-quarter day level of production.

in a negligence regime will not face any sanctions so long as he is taking the due care level of precautions, thus he will only consider the cost of precautions in comparison to the benefits received at each level of production and will run the plant for full days.

Another drawback of a negligence regime, as opposed to strict liability, is that uncertainty can influence employee behavior in a suboptimal manner (although in the direction of taking too much rather than too little care).[115]

A final drawback of the negligence standard is that litigation costs could be higher than under a strict liability standard. Under strict liability, the court must only determine whether a violation occurred and whether the alleged offender has a recognizable defense, whereas under negligence, the court must also inquire into the level of care taken by the alleged offender.

Although these drawbacks to a negligence standard admittedly exist, it must be considered whether they are outweighed by the drawbacks of the current strict liability standard, thus positing the negligence standard as superior.[116]

[115]Shavell points out that the fact that a court might err in assessing the employee's level of care, and/or uncertainty over the due care level that will be applied by the court, can induce the employee to take socially excessive levels of care (assuming that the due care standard is set optimally). Shavell, *supra* at Ch.15: 5-7.

[116]The argument against the negligence standard in *S. Rep* 684, *supra*, that adopting such a standard under the Act would call into question the strict liability standards applicable to other statutes dealing with food safety (such as the Filled Milk Act, the Egg Products Inspection Act, the Poultry Products Inspection Act and the Meat Inspection Act), and "ultimately lead to similar changes" is no argument at all. Rather, the statement merely suggests that if a negligence standard is recognized as superior to a strict liability standard for violations of the Act, it is only rational that it might also be recognized in the context of similar statutes.

Part VIII

Conclusion

History alone does not dictate that we should continue to apply strict criminal liability to corporate agents in the food and drug industry. If there are better means of accomplishing the same ends, it is time we reconsider our current means and refrain from needlessly subjecting (1) the industry to suboptimal participation, (2) corporate agents to the danger of serious personal repercussions, and (3) the criminal justice system to delegitimizing forces. This paper has outlined alternative methods by which liability could be imposed without seriously disrupting the deterrent effect on corporate agents or the levels of safety in the industry. There is no reason not to at least give these methods, or others that may be proposed, consideration and aim to make improvements over the current situation.