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AN ECONOMIC ANALYSIS OF FOOD AND DRUG LAW: Selected Topics in FDA Enforcement

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Introduction

While the FDA has broad authority to enforce the FDCA, some argue that the FDA is not doing enough.¹ Yet many attempts by the FDA to expand its authority or to try novel, and possibly more effective methods, have been blocked by the courts.² Sometimes, this judicial curtailment of FDA authority has led to disastrous results. For example, in 1977, on the basis of new scientific studies, the FDA twice tried to seize an amino acid called L-tryptophan, which was labelled as a dietary supplement; both times the District Court involved prevented the seizure.³ As a result of these two court losses and the concomitant expenses the FDA stopped attempting to regulate the marketing of amino acids to consumers.⁴ L-tryptophan continued to be produced and sold as a dietary supplement until 1990, when it was shown to cause an illness called Eosinophilia Myalgia Syndrome (EMS).⁵ As a result of L-tryptophan remaining on the market, thirty-eight people have died and 1500 people have been injured. Moreover, two years after the EMS outbreak was caused by L-

¹See, e.g. Arthur Kalett & F.J. Schlink, 100,000,000 Guinea Pigs (1933) (Peter Barton Hutt & Richard A. Merrill, Food & Drug Law: Cases and Materials 2d Ed. (1991). f hereinafter CB1 at 1148, 1149).

²See, e.g. U.S. v. C.E.B. Products, Inc., 380 F. Supp. 664 (N.D. Ill. 1974) (CB 1178) (holding that FDA is without authority to request a judicially-ordered recall); U.S. v. Parkinson, 240 F.2d 918 (9th Cir. 1956) (CB 1175) (holding that FDA is without authority to request restitution to purchasers of products in violation of the FDCA).

³Carter Anne McGowan, Learning the Hard Way: L-Tryptophan, the FDA, and the Regulation of

⁴ Id.

⁵ Id.

tryptophan, it was revealed that although eighty percent of [the] EMS cases showed some improvement, over sixty percent of the patients had symptoms characterized as moderately to extremely severe, and only ten percent had completely recovered.⁶

Amino Acids 3 Cornell J.L & Pub. Pol'y 383, (1994). p.2

The rationales used to deny granting broader authority to the FDA have focused on technicalities:⁷ the literal language of the FDCAZ whether private individuals were named as parties to the action;⁸ and in the L-tryptophan cases, a clerical error which resulted in L-tryptophan erroneously appearing as a nutrient/ dietary supplement rather than as a food additive in 1977's Code of Federal Regulation.⁹ What is lacking in these cases is an economic analysis of the issues. When technicalities govern, and concerns of efficiency and social optimality are ignored, society will inevitably be harmed. This fact is evidenced by the L-tryptophan tragedy.

In this paper, I hope to introduce the world of Law & Economics to the world of FDA enforcement. By no means is this an effort to analyze every problem dealing with the subject of FDA enforcement. Similarly, the purpose of this paper is not to arrive at solutions for problems, although I will suggest some. Most of the solutions to the topics I will discuss can only be made on a case-by-case basis. Rather than attempt that feat, this paper seeks to establish a rudimentary framework for thinking about the problems of FDA enforcement by

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Id.

⁷ See C.E.B. Products CB at 1178.

⁸ See Id. CB at 1175.

⁹ McGowan, *supra* note 3.

analyzing five areas. Section A will discuss FDA sanctions and how they impact on incentives to act in a socially efficient way. The remaining four sections will take a more in depth look at four of the individual enforcement mechanisms. Section B will deal with inspection, C with seizure, D with criminal liability and the Guaranty Clause,¹⁰ and E with recall. Once again, this paper is only a beginning, not an end.

A. Preserving Deterrence Problems With Incentives

In an ideal world, a manufacturer M would only act in socially beneficial ways. Expressed in a different way, if an activity causes more harm to society than it benefits society, we would not want M to engage in that activity. If we want M not only to take the proper care when acting, but also to engage in the activity at the socially optimal level, then we should hold M strictly liable to pay for all the harm that it causes, i.e., pay for the costs it imposes on society regardless of fault.¹¹ There are two ways we can make M pay for the costs it imposes on society. The first is harm-based liability, which means that we will make M pay each time it causes harm. The second is act-based liability, which means that every time M acts in a certain way we will make it pay. Under either

¹⁰§303(c) of the FDCA.

¹¹Shavell, *Principles of Economic Analysis of Law* §13.3.5. The difference between care level and activity level can be explained by example: let us say that for a driver to take proper care, she must wear a seatbelt, not consume alcohol, check her rear view mirror periodically, follow all traffic laws, and take a 5 minute rest stop for every 3 hours she drives. Her activity level, on the other hand, is how much she drives per day; she may drive 1 hour per day or 10 hours. Under a negligence or fault-based system, she would be liable only if she violates a standard of care. Assuming she does not, she would never pay for any harm done. This is true no matter how often she drives, even though by driving 10 hours a day instead of 1 hour per day, she increases the probability that she will be involved in an accident, merely by being on the road so many hours (and by increasing congestion). Under a negligence, or fault-based system, assuming M, the manufacturer, took the optimal level of care, it would engage in [its] activity to too great an extent because, unlike under strict liability, [M does] not pay for the accident losses it cause[s]. *Id.*

system, the goal is to force M to pay for the costs its acts impose on society. As a result, M will act only if the benefit it expects to gain outweighs the costs it expects to impose. Therefore, under a harm-based liability system, M should pay for any harm that it ever causes. Under an act-based liability system, M should pay for the expected harm due to the act, regardless of whether any harm actually occurs.¹² In either regime, the firm's expected p. liability is the expected harm.¹³ In either system, therefore, will act only if [its] expected benefit exceeds the expected harm, that is [MI will act if and only if that is socially desirable. Hence, the optimal outcome will result.¹⁴

Our current FDCA enforcement system is a combination of act-based and harm-based liability. Private individuals can sue M under our tort law and try to recover for any harms done to them by M. While some jurisdictions employ a fault-based liability system for general torts, many jurisdictions treat harms caused by violations of the FDCA as negligence per se.¹⁵ In reality, such as system is a strict-liability regime for harms caused by violations of the FDCA. Our enforcement system also has elements of an act-based liability system. For example, the FDA, through the U.S. Attorney's Office, can bring a criminal suit against someone who commits an act which violates the FDCA.

¹²Shavell, Principles of Economic Analysis of Law §21.2.8. An expected variable is a probability weighted average. Using two examples is probably the easiest way to explain. If I flip a coin and someone offers me \$100 if it lands head, 50 percent of the time I will win \$100, and 50 percent of the time I will win \$0. If I flip a coin twice, on average I will win once and receive \$100. Therefore, if I flip the coin one time, it is said that my expected winnings is \$50. The equation to determine this is $50\% \cdot 100 + 50\% \cdot 0 = 50$. Expected variables are as complicated as the number of possible outcomes. If I played a game where there was a 10 percent chance of winning \$10, a 30 percent chance of winning \$100, a 5 percent chance of winning \$1000, and a 55 percent chance of winning nothing, my expected winnings =

¹³Shavell, Principles of Economic Analysis of Law §21.2.

¹⁴Shavell, Principles of Economic Analysis of Law §21.2.2.

¹⁵See, e.g. Orthopedic Equipment Co. v. Eutsler 276 F.2d 455 (4th Cir. 1960)(CB 1220)

If a drug is mislabelled, the manufacturer can be punished even if no harm ever occurs. Other FDA enforcement mechanisms, such as seizure, injunction, voluntary recall, and publicity can be employed whenever firms are engaging in acts which violate the FDCA.

As stated previously, for a manufacturer M to act in a socially optimal manner, M's expected liability for engaging in an activity should be equal to the expected harm caused by this activity. We can determine mathematically what the expected liability is by looking at each possible source of liability and multiplying it by the probability of each source occurring. Let EL^{16} be the Expected Liability that M faces. Let t be the probability that private individuals wins a tort claim against M. Let T be the cost to M if the private individual does win a tort claim. Let f be the probability that M receives a criminal fine. Let F be the amount the fine is, if a criminal fine is

$.1.10 + .3.100 + .05.1000 + .55.0 = \81 . Expected Harm, therefore would be found by multiplying the probability that the act will cause harm by the amount of actual harm caused if harm occurs. $p.5$ imposed. Let $s, i, r,$ and p be the probabilities that M faces a seizure, an injunction, recall, or publicity respectively. Let $5, I, R,$ and P be the actual cost that M faces if it does face a seizure, an injunction, recall, or publicity, respectively. Then $(EL = tT + fF + sS + ii + rR + pP)^{17}$ If (EH equals the expected harm to society caused by M's action, then ideally, $(EL = (EH = tT + fF + sS + il + rR + pP$. and thus, M will act if and only if acting is socially desirable.¹⁸

¹⁶Let CE be the symbol for Expected.

¹⁷See *supra* note 12.

¹⁸It should be noted that a manufacturer will rarely, if ever, face all six possibilities at once.

One potential problem with having this dual system of sanctions (tort and FDA initiated) is the possibility of double punishment. If there is a type of violation where a tort suit is very likely to be brought, and the plaintiff will recover for all of his harms, then the expected sanction under the tort system alone will adequately preserve incentives. If the FDA also initiates sanctions against the firm, then the total expected sanction the firm will face may exceed the expected harm. Firms will be over-deterred in efforts to avoid harm, and will inefficiently take too much care.¹⁹ There are, however, many reasons why the tort system might fail to hold M liable for the expected harm it causes. A very incomplete list of reasons is: 1) the harm is not likely to be attributed to the product; 2) the harm is sufficiently small as to make bringing suit not worthwhile; 3) any of the many other reasons why people may not bring suit; 4) the firm may be able to settle the dispute for a price less than the harm caused; and 5) the tort award does not factor in all harms to the individual such as pain and suffering, mental anguish, or other non-pecuniary costs. In such situations, where the tort system fails to completely reflect the expected harm, a supplemental sanction initiated by the FDA, if properly calculated, would ensure proper care and activity levels.²⁰

While it is conceivable that over-deterrence could be a problem, in all likelihood, under-deterrence is a more realistic and more widespread problem.

Either the goods will be seized, or there will be a recall, etc. Many times it will be useful to think of (EL as equal to the probability that M will face liability multiplied by the actual liability L it will face if it does face liability.

¹⁹It is beyond dispute that for a company to invest \$10,000,000 to avoid \$100 in harm is just as wasteful as failing to invest \$100 to avoid \$10,000,000 in harm. Both courses of action waste \$9,999,900.

²⁰Having two sets of litigation costs, however, would seem to be inefficient in that it entails duplicative administrative costs.

Our current system is very troublesome in terms of preserving adequate incentives to act optimally. While the maximum fines provided for by statute are very steep,²¹ in practice, the fines are often paltry. For example, in U.S. v. Park²² the CEO of a company was convicted of allowing food to be stored in a warehouse infested with rodents, and of allowing the food to be exposed to contamination by rodents. The FDA charged the defendant with five counts of causing food adulteration. The CEO was convicted and fined \$50 for each count. This sanction is a travesty. Since adulteration would rarely result in tort liability (consumers are ignorant of most adulteration, and would rarely bring suit unless serious harm resulted that could be attributed to the product), and since the FDA has very limited resources, and cannot be everywhere at once, the probability that the Company or the CEO would have faced sanctions was very small. Let the probability that a company or individual faces any sanctions whatsoever be q , and q is much smaller than 1. Let (EH) equal the Expected Harm caused by the company's rodent infestation.²³ Let S equal the total p.7 sanction that the company or individual receives if it or he receives a sanction. To achieve optimality, we want the expected sanction to be equivalent to the

²¹See 18 U.S.C. §3551 (CB 1164-65)

²²421 U.S. 658 (1975)(CB 1155).

²³Among the harms to society, some are: 1) any illnesses caused by the ingestion of adulterated food; 2) loss caused by suboptimal purchasing (consumers would buy less of a product if they knew it were adulterated); and 3) by taking less care and allowing rodent infestation, the company avoided the cost of keeping the warehouse free from rodents. The company was therefore able to market its product at a lower price. This result reduced demand for competitors' products and hurt competitors' economic viability. This harm caused by the company unfairly gaining a larger portion of the market must be factored into the costs of defendant's actions. By not taking care, the defendant's company achieved private gains that would not be shared by society, namely swiping a larger share of the market than it deserved. This type of private gain does not add to social wealth, it merely redistributes it. We want the company to engage in activity when the benefit to society caused by its actions outweighs the costs to society, not when the benefit to M caused by its actions outweighs the costs to society. Any perverse

expected harm. Therefore, we want: $q \cdot S = (E) \cdot I$. As a result, when Mr. Park received a sanction for his violations, the sanction, 5, should have been $(EH) / q$.²⁴ Considering the small likelihood that a company or an individual is sanctioned, if companies believe that they will only face, if prosecuted, a fine totalling \$250, their Expected Liability is minimal and their incentives to take care cannot be preserved.

Others have echoed this view. Director Campbell of the FDA has stated exactly what the Park case shows: that the pure food laws provide for such mild penalties that a manufacturer could pay the fines imposed... and continue to do wrong.²⁵ Two authors, Arthur Kallet & F.J. Schlink, have argued that since the fines actually assessed are too small and since it is the publicity [the companies] fear, the FDA should issue information to the public about which companies are violating the act.²⁶ Since negative publicity could destroy a company, even though the probability of receiving this sanction would be small, the Expected Liability would still be high. Furthermore, the cost of publicity to the FDA might be sufficiently small and yet have such a strong deterrent effect on companies that this sanction might be very effective. The problem with this sanction is that the effect of publicity might be difficult to gauge. It would be very hard for the FDA to control the private gain that the

²⁴Notice that since q is always less than 1, the sanction imposed on the defendant should always be higher than the expected harm caused. Moreover, the smaller the probability of liability is, the greater the sanction needs to be. For example, assume the probability that any one company actually receives a sanction for infestation is .01. (This may not be an unrealistically low figure considering how wide-spread infestation is, as evidenced by FDA tolerance levels). If the company causes \$1,000 of harm to society, then the company should receive a fine of \$100,000, or 100 times the magnitude of the harm caused to society.

²⁵Arthur Kallet & F.J. Schlink, 100,000,000 Guinea Pigs (1933)(CB 1194).

²⁶Id.

company achieved (such as stealing a greater portion of the market by not taking care), which is not shared by society must be factored into the harm to society to preserve proper incentives. Cf. Shavell, Principles of Economic Analysis of Law §20.1.2. p. effect publicity has on a company. We don't want Coca-Cola to be destroyed if one inspector finds one fly near the processing machines. If the FDA can't control the damage that publicity would cause, using such a device might over-deter firms and encourage firms to take too much care.

Unfortunately, the other enforcement techniques also have major problems. Under seizure, the worst that can happen is loss of the value of the shipment, crate, or carton of confiscated goods. Seizure is a sanction, therefore, that is not tailored to equalling the expected harm caused by a company's violation. Rather, it is a loss of the production costs of the seized product. Furthermore, it is very expensive for the FDA to institute a seizure action, and thus very draining on FDA's limited resources.²⁷ Under recall, as opposed to under seizure, the additional costs of actively recalling the products is imposed on the producer, and recall causes negative publicity. It therefore imposes a greater liability on the producer while avoiding the severe costs to the FDA. Recall suffers, however, from the same defect that seizure suffers from, since recall is not tailored to the harm caused.²⁸ Restitution, though, has a number of advantages over seizure.²⁹ Under restitution, the company loses the market

²⁷See infra part C. for a discussion on when seizure is efficient.

²⁸See infra part D. for a broader discussion on recall.

²⁹Courts have rejected the use of restitution as an enforcement device. See U.S. v. Parkinsor, 240 F.2d918 (9th Cir. 1956)(CB 1175). The Parkinson court held that the FDCA did not authorize such a remedy, and since no individuals were named as parties, restitution would be inappropriate. However, I am solely concerned with whether restitution would be an efficient remedy in certain cases.

price for the product rather than merely the production cost. Furthermore, producers are sanctioned for the amount of product consumed rather than solely for the amount that the FDA was able to seize. However, restitution also has a few drawbacks. It does not stop the tainted product from continuing to reach the public. It also imposes a cost on the FDA to set up a system for disbursing the recovery to consumers.³⁰ Finally, restitution also fails to tailor liability to expected harm. The last method of enforcement I will mention in this section, the regulatory letter, has the advantage of being a very cheap way of warning companies into compliance. However, the regulatory letter imposes no real sanction on the company. A company committing minor violations, which are of the type most likely to receive regulatory letters, has little incentive to correct violations before receiving such a letter, since no harm is caused to the company by being punished with this device.

Fortunately, [un] early 1991, the [FDA] embarked on a highly publicized policy of enhanced enforcement of the FDCA in an effort to restore 'the credibility and the integrity' of the FDA. Efforts were focused on widely-known companies and consumer products.³¹ Furthermore, the criminal provisions of the Act have been relied upon more heavily in recent years.³² Moreover, in the first few months after the 1992 Generic Drug Enforcement Act, the FDA won almost 40 convictions and \$19,000,000 in criminal fines.³³ It remains to be seen whether this renewed effort will adequately increase expected sanctions

³⁰Id. at CB 1176-77.

³¹31 Am. Crim. L. Rev. 629, 641.

³²Id. at 643.

³³Id. at 645.

to combat eroded incentive structures. While this renewed effort can only be praised, the FDA should take this opportunity to consider some of the above concepts when determining what methods of enforcement are to be employed and what magnitude of sanctions are to be brought.

Because the FDA is currently targeting widely-known companies, a final question is whether this selective enforcement is efficient. From a legal standpoint, [ut is well established that [the FDA] has discretion to initiate enforcement action against fewer than all of the firms engaged in similar unlawful conduct.³⁴ From an efficiency perspective, this system is not on such sure footing. Selective p.10 enforcement is not necessarily problematic. It is much less costly for the FDA to be able to initiate proceedings against only a few violators. While this reduces the probability that any one company will face sanctions, as long as the FDA matches the reduction in the likelihood of sanctions with a corresponding increase in the actual sanctions imposed, then the expected sanctions a firm faces will remain the same, incentives will be preserved, and FDA resources conserved. It also makes sense to go after widely-known companies because the publicity surrounding such actions will ensure that the limited action will have the maximum impact.

There are problems, however, with the current system of selective enforcement. If the FDA primarily goes after widely-known companies, the probability that those widely-known companies will face prosecution will be high, while the lesser-known companies will face only a very small probability

³⁴CB1045.

of facing liability. If drastic adjustments are not made to the actual sanctions imposed, lesser-known companies will have little incentive to take care because their expected sanction will be so low (as a result of the minimal probability of facing sanction), while widely-known companies will be forced to take care. Not only may this system encourage many violations from lesser-known companies, but it may also put widely-known companies at a competitive disadvantage.³⁵

Another problem with the current system of selective enforcement is that the FDA has announced which categories of violations it will focus on. Sam D. Fine, who had once served as FDA Associate Commissioner for Compliance, explained that the FDA will focus prosecution efforts on a continuation or repetition of violations over a period of time, or a single gross or deliberate violation including p. flagrant, life-threatening, or intentionally false or fraudulent violations.³⁶ While it certainly makes sense to focus limited resources on the most dangerous and harmful violations, or the most culpable conduct, such a system creates incentives to allow minor violations or to be willfully blind to such minor violations. If prosecution, or sanctions, are so rare for minor violations, then in order to preserve incentives, actual sanctions imposed for minor violations need to be very high, and may in fact need to be higher than

³⁵Such companies will be at a competitive disadvantage because they will have to expend more resources to ensure compliance. Such expenditure will result in a higher priced product. If we assume that consumer information is imperfect. (which is likely since imperfect consumer information and the corresponding need to protect consumers are the principle justifications for the FDCA,) then consumers will see the higher price, but will not translate that price into the greater safety or higher level of sanitation that the price represents. All consumers will see is a higher price, and thus will consume the products of lesser-known companies at a greater rate.

³⁶Sam D. Fine, *The Philosophy of Enforcement* 31 F.D.C. L.J. 324 (1976)(CB 1149). See also Government's Brief in *U.S. v. Park* 421 U.S. 658(1975), at pp. 30-32 (CB 1160, 1161).

actual sanctions for major violations.³⁷ Unless we are willing to tolerate minor violations of the FDCA, something must be done to preserve the incentives to avoid such violations.

B. Inspections

The statutory authority to inspect is explicitly given by §704, which provides that inspectors can enter and inspect, at reasonable times and within reasonable limits any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction,... any vehicle, being used to transport or hold such [items] in interstate commerce.³⁸ Inspectors can ask to see all pertinent equipment, finished and unfinished materials, containers, and p.12 labeling therein.³⁹ And in the case of prescription drugs or restricted devices, inspectors can also see all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether such items are adulterated or misbranded within the meaning of this Act,... or otherwise bearing on violation of this Act.⁴⁰ Furthermore, §301(f) of the FDCA prohibits [the refusal to permit entry or inspection as authorized by §704. The FDA's ability

³⁷For example, if the probability of receiving a fine for a minor misbranding violation that causes \$100 in societal harm is one in ten thousand, a defendant who does get sanctioned should be fined \$1,000,000. Such a fine will result in the defendant's expected sanction optimally equalling the expected harm to society. But if the probability of receiving a fine for a major infestation problem that causes \$250,000 in societal harm is 0.50, then a defendant who does get sanctioned for this offense should be fined \$500,000. Although these fines would be appropriate in order to preserve incentives, the likelihood that society would accept such a counter-intuitive system seems dubious. One possible way to institute this low probability/high sanction system is to allow insurance against such fines. For an explanation of how insurance could make this system work, see the discussion below on why recall insurance would be efficient, *infra* part E.

³⁸§301(a)(1).

³⁹*Id.*

⁴⁰*Id.*

to inspect all factories, warehouses, or other facilities falling under the jurisdiction of the FDA is crucial to successful enforcement of the FDCA. In 1952, the Supreme Court noted that it is from factory inspections that about 80 percent of the violations [of the FDCA] are discovered, [and also stated] that the small force of inspectors makes factory inspections, rather than random sampling of finished goods, the only effective method of enforcing the [FDCA].⁴¹ Courts have held, however, that an inspection pursuant to a [§704] notice to inspect is authorized only when there is a valid consent. If consent is withheld, a separate violation of the Act occurs and the FDA inspectors are required to obtain a[n administrative] warrant before the inspection can proceed.⁴² The rationale for this holding is that because the FDCA punishes refusals to permit inspections by imprisonment up to one year, or a fine of not more than \$1,000, or both, consent must be obtained.⁴³

This system, which forces inspectors to get consent or a warrant, is problematic. It would be inefficient for FDA inspectors to get a warrant before every attempt at inspection. The required FDA manpower would be great and would result in substantial costs; FDA inspectors have plenty of better things to do than waste time getting warrants every time they want to do a routine inspection. There are also p.13 substantial costs in providing an administrative probable cause hearing for every inspection request. Furthermore, few companies or individuals would be willing to refuse consent if asked: 1) it is a crime

⁴¹United States v. Cardiff 344 U.S. 1952 (1952)(CB p.liO2).

⁴²United States v. Jamieson-McKames Pharmaceuticals, Inc. 651 F.2d 532 (8th Cir. 1981)(CB p.1104, 1106). See also U.S. v. I.D. Russell Laboratories 439 F. Supp. 711 (W.D. Mo. 1977).

⁴³Jamieson-McKames Pharmaceuticals 03 at 1106.

to refuse to allow the FDA to inspect; 2) since the FDA would easily be able to obtain a warrant, the company or individual would rarely gain anything by refusing consent; and 3) in most cases, the easiest way of dealing with the FDA is to be reasonable, not look like you're trying to hide something, and keep the FDA inspector happy. In sum, if there are any benefits gained by having the warrant in the rare case where it would be necessary, such benefits would be far outweighed by the costs of getting one in every situation.

It is also inefficient for an inspector to go to an establishment and hope that the owner, operator, or custodian will not refuse consent.⁴⁴ Such a system reduces incentives to take care. If I am the owner of a food storage facility, I know that if an FDA inspector comes and requests to inspect my facility, I can refuse consent. If I exercise this choice I will: 1) be subject to a *maximum* of 1 year imprisonment, a fine of up to \$1,000, or both; and 2) force the inspector to get an administrative warrant. My cost of refusal is the expected fine or prison sentence. My benefit is what I can do with the time it takes for the inspector to procure a warrant. I can clean the factory, burn or otherwise destroy foodstuff that is clearly in violation of the FDCA, or try to cure violations. If by forcing the inspector to get I warrant I can eliminate or hide enough violations, then it might be worthwhile for me to refuse consent. Let W be the average amount of time it takes to get a warrant. Let the Expected Punishment⁴⁵ I will personally receive if I consent to the inspection be $(EP1)$.⁴⁶

⁴⁴[Consent must be given by the 'owner, operator, or custodian' and not by a subordinate employee. U.S. v. Maryland Baking Co. 81 F. Supp. 560 (N.D. Ga. 1948)(CB 1110, n.3).

⁴⁵See supra, note 12.

⁴⁶See supra, note 16. So if $P1$ is the actual punishment I would receive had I consented to inspection, been charged with violations, convicted, and sentenced, $(EP1)$ is the Expected

Let $(EP_2$ be the Expected Punishment I will personally receive if I refuse p.14 consent, violate §301(f), and use the time W to eliminate or hide violations. Assume that I will not be reducing the probability that I am convicted, (in fact, by refusing to consent, which is a clear violation, I am only increasing the probability of conviction). It is possible that I may reduce the actual punishment enough that my expected punishment will decrease, despite any increases caused by my refusal to give consent. If $(EP_2 < (EPI$ then it will be efficient, from my point of view, to refuse consent. Because I know in advance of any inspection that I can refuse consent, I may have a decreased incentive to eliminate certain quickly remedied or easily hidden FDCA violations. In those situations, I will only face the lesser $(EP_2$, instead of the more severe $(EPI$.

The only possible justifications for allowing a firm to refuse consent seem weak. The statute already requires that an inspection must be at reasonable times and within reasonable limits so that inconvenience is minimized.⁴⁷ Also, if an inspector is using inspection to harass, refusing consent only exposes oneself to criminal sanction. Since the FDA inspector can always get a warrant to do a routine inspection if consent is refused, the only possible justification for a firm to refuse consent is to try to hide violations. The consent requirements should therefore be eliminated. As long as the FDA inspector provides notice and complies with the other statutory requirements, consent should be sought (to keep things civil), but not required.

C.Seizures

Punishment I would receive. CEI^1 , as explained in *supra*, note 12, is found by multiplying the probability that I am convicted by the actual punishment I receive if I am convicted.

⁴⁷Id.

Section 304 of the FDCA grants the FDA the authority to seize items that violate the Act. The FDA can initiate a suit seeking seizure and condemnation of the item in question. Preliminary seizure can be authorized.⁴⁸ The owner then has the p.¹⁵ opportunity to appear as a claimant and to have a full hearing before the court.⁴⁹ In the hearing, the government must prove its case by a preponderance of the evidence.⁵⁰

Seizures can be very useful. In an unfortunately large number of instances, however, seizure is a wholly ineffective and inappropriate remedy that needs to be supplemented by more efficient approaches.⁵¹ Seizure can be very expensive, represent[ing] a substantial expenditure of government resources.⁵² Yet, many seizures,..., include only a small amount of the total goods involved.⁵³ Furthermore, for a ten year period up to 1973, 13 percent of [FDA] seizure recommendations were never executed because the product had been moved or consumed during the time taken to complete [seizure] procedures.⁵⁴ Finally, and perhaps most troubling, the impact of a single seizure of a small amount of a product can be effectively blunted simply by filing a claim and engaging in the usual pre-trial discovery. The inventory of the offending product can then be relabeled, or exhausted without change, and at that point a consent decree

⁴⁸Parke. Davis & Co.. v. Califano 564 F.2d 1200(6th Cir. 1977)(CB 1127, 1128). Some Courts have held that seized product should not be returned to the claimant pending final determination. See U.S. v. Article of Device... 110 V Vapozone... 194 F. Supp. 332 (N.D. Cal. 1961)(CB 1123, n.1).

⁴⁹Ewing v. Mytinger & Casselberry. Inc. 339 U.S. 594 (1950).

⁵⁰See. e.g. U.S. v. 60 28-Capsule Bottles... UnitroL 325 F.2d 513 (3d Cir. 1963)(CB 1130).

⁵¹Peter Barton Hutt, Philosophy of Regulation Under The Federal Food, Drug and Cosmetic Act 28 F.D.C. L.J. 177 (1973)(CB 1136).

⁵² Id.

⁵³ Id.

⁵⁴ Id.

can be accepted or the claim withdrawn and the case forfeited.⁵⁵

Since seizure is far from a perfect remedy, it would be useful to determine when seizure would be efficient. The simple answer is that the costs and benefits of each alternative technique of enforcement should be weighed and the option which maximizes social utility should be used. To develop a more intricate model, I will p.16 use a hypothetical. Ms. A raises cattle. FDA inspector Mr. B does some routine preliminary tests on A's cattle. These tests seem to indicate that 100 cows probably contain trace residues of illegal antibiotics.⁵⁶ If such residues are proved to be present, the cows will be condemned. At this point, B has two options: 1) B can go and get a warrant to seize the 100 cows; or 2) he can talk with A, describe his findings, explain that he does not want to have to seek an injunction that would close down A's business or seek criminal charges that could result in A receiving a prison term, and informally ask that A separate these cows and make sure that they are not used for meat.⁵⁷

In choosing between these options, B needs to determine what the costs and benefits of seizing the cows are. The first cost is the actual expense E of seizing the cows. As stated previously, seizures can be very expensive. There are administrative costs including the time wasted obtaining the authority to seize, using up court time, coming back, and seizing the product. And while B, in this case, would not have to track down all of the adulterated product in many states, and initiate seizures in each district, the seizure of 100 cows would

⁵⁵ Id.

⁵⁶ Assume that these are preliminary field tests and are not 100 percent accurate.

⁵⁷ While there are normally other options, assume that they are either less efficient or not available.

be expensive. Transportation costs, food costs, and storage costs (whatever that means in terms of large livestock) would all be steep.

The second cost from seizure is any damage to the cows during the seizure, and the confiscation period caused by the FDA. Cows may be injured from transportation, or may become sick, lose weight, or die as a result of the FDA, rather than the owner, caring for the cows. Let $(ED$ be the Expected Damage done to the cows from seizure. To keep this problem simple, let us assume that there is only one level of damage D , and a certain probability q that if B seizes the cows, damage D will occur.⁵⁸ Therefore, $(ED = q \cdot D$. However, this damage only affects society if the FDA p.17 would lose on their seizure and condemnation suit. If the FDA wins, the cows would have to be destroyed and any damage to the cows caused by the seizure is irrelevant. Only if A wins and could use the cows would any damage to the cows matter. Therefore, let p equal the probability that the FDA would lose its condemnation suit (and thus $i-p$ equals the probability that the FDA would win). The cost to society from damage of seizing the cows is the probability that the FDA would lose multiplied by the expected damage caused if B seizes the cows, or $p \cdot (ED = p \cdot q \cdot D$.

Finally, the last cost of seizure is the damage done to society if the seizure fails because while B was getting authorization to seize, the cows were moved or put into commerce.⁵⁹ Let r be the probability that even if B attempts

⁵⁸In reality, there may be many different levels of damage. There might be a 10 percent chance of \$100 of damage occurring, a 30 percent chance of \$1000 of damage occurring, and a 5 percent chance of \$10,000 of damage occurring. In any one seizure, we can therefore expect an average damage of $0.1 \cdot 100 + 0.3 \cdot 1000 + 0.05 \cdot 10,000 = 810$. $(ED$ would, in this case, equal \$810.

⁵⁹Cf. supra note 23 and accompanying text.

a seizure, A will be able to move or sell the cows and avoid seizure.⁶⁰ Let H equal the harm to society from illness or built up resistance to antibiotics, which will occur if A can avoid seizure and the cows enter into the stream of commerce.⁶¹ Therefore, even if B tries to seize the cows, there is a probability r that H harm to society will occur. Therefore, p.18 the Expected Harm to Society caused by the failure obtain the seizure in time is $(E\text{-}I\text{-}t = r \bullet H$. However, harm to society only occurs when the failure to seize due to delay affects the end result. If A would have prevailed in the condemnation suit, then the cows could have been put lawfully into the stream of commerce. Then, the fact the FDA failed to seize the cows because of the delay in getting authorization would be irrelevant. Had the cows been successfully seized, A would have won the condemnation suit, and the cows would have reached the market anyway. Only when the FDA would have won the condemnation suit, and could have prevented the harm to society, but failed to do so because B unsuccessfully tried seizure instead of a more expedient or more effective alternative, is harm caused by the attempted seizure. Therefore, since we stated above that the probability that A would not win the condemnation suit is 1-p, it is only with that probability that the Expected Harm was caused by the seizure. We can summarize this by saying

⁶⁰While the option of administrative detention might be possible, which would lower the probability that A could move or put the cows into commerce, all that would do is reduce r. However, since the FDA currently does not have this power, and would have to rely on the states, I will omit such a consideration. See CB 1137.

⁶¹Since [m]any seizures, include only a small amount of the total goods involved, then the harm prevented by keeping that small amount off the market might be small. Hutt, supra note 49. Furthermore, it should be noted that society is harmed even when there is only economic adulteration or mislabeling of products. Consumers misallocate funds (spend more money than they would optimally spend on products that optimally they might not buy) and legitimate businesses are hurt since the violator will capture a larger share of the market than is optimal. This will 1) hurt other businesses' ability to succeed and invest in research and development of socially beneficial advances and 2) encourage other businesses to cheat in order to compete.

that the Harm to Society caused by attempting seizure is $(1-p) \cdot r \cdot H$. To conclude, the total cost of seizure can, therefore, be represented by:

$$E + p \cdot (ED + (1-p) \cdot EH) = E + p \cdot q \cdot D + (1-p) \cdot r \cdot H$$

We can similarly analyze the benefits of seizure (or the costs of not seizing). If B decides to trust A not to put the cows into stream of commerce, then there is a probability s that A will cheat and get them on the market. If the cows enter the market, harm H (the same H used above) will occur. Once again, however, harm H is only caused by the B's decision not to seize if A cheats and A would have lost the condemnation suit. As similarly explained in the discussion on the Expected Harm to Society caused by the delay in obtaining seizure, if A would have won the condemnation suit, then the cows could have gone on the market anyway. Thus, any harm to society caused by A cheating and breaking her promise would be caused regardless of that violation of B's trust. Therefore, let the Expected Harm caused by B choosing not to seize and A cheating equal (EH_c) which would equal H occurring with a probability of s . And since this Expected Harm is only relevant or only factored into the cost to society when A would not have won the condemnation suit, (or with probability $1-p$), this cost to society of not seizing is $(1-p) \cdot (EH_c) = (1-p) \cdot s \cdot H$.

The other cost of not seizing is any harms caused by tampering with the evidence. If A retains control over the cows, it may be possible for her to tamper with the cows, or somehow eliminate the presence of the residues in the cows. Assuming that this is possible in some situations, tampering may reduce the probability that the FDA is able to meet its burden of proof in the

condemnation suit, i.e., tampering may reduce the probability that the FDA is able to successfully bring criminal charges against A. Let t be the probability that A is convicted of criminal charges if B seizes the cows. If B does not seize the cows, and B thus gives A an opportunity to tamper, then let x be the positive amount by which the probability that A is convicted is reduced (if B's failure to seize the cows reduces, from 50 percent to 40 percent, the probability that A is convicted, then $x = 0.10$).⁶²

Assume that if convicted, A will in either situation receive Punishment P . Therefore, A's expected punishment under seizure is $t \cdot P$, but A's expected punishment if B doesn't seize is $(t-x) \cdot P$. If FDA inspectors always seize, A's Expected Punishment, or $(EP_1 = t \cdot P)$. A, therefore, will only violate the FDCA if her Benefit B from violating the act is greater than her expected punishment, or $B > t \cdot P$. Now assume that overall, inspectors seize with probability y and do not seize with probability $1-y$ (the probability, therefore, that inspectors either seize or do not seize is $y + 1-y = 1$). Under this second regime, A's Expected Punishment, EP_2 equals the weighted averages of the possible outcomes, or:

$$(EP_2 = y \cdot [t \cdot P] + (1-y) \cdot [(t-x) \cdot P])$$

A successfully tampers with the cows are factored into the value of x . The greater those probabilities are, the greater the value of x is.

$$\begin{aligned} \text{Combining like terms: } & y \cdot t \cdot P + t \cdot P - y \cdot t \cdot P - (1-y) \cdot x \cdot P = \\ & = t \cdot P - (1-y) \cdot x \cdot P \end{aligned}$$

⁶²For simplicity, the probability that A attempts to tamper with the cows and the probability that

Since both $(1-y)$ and x are defined as positive probabilities and, thus, are both greater than zero:

$$= t^*P - (1-y).x.P < tP \text{ Therefore, since } t^*P = (EP_1:$$

From this result we can see that under a policy where seizure does not occur every time, and where violators are given the opportunity to tamper, violators will face a lower Expected Punishment. A will have an increased incentive to violate the FDCA because under a 100 percent seizure regime the Benefit B, gained from violating the act, had to outweigh $(EP_1$; now B must only be greater than $(EP_2$.⁶³

Because a regime where seizure always occurs eliminates the opportunity to tamper, which preserves the higher incentives to take care, B's decision whether to seize or not will have a marginal effect on incentives. A decrease in the incentive structure will increase FDCA violations and cause more harm to society. Let R be the cost to society which results in the marginal decrease in incentives caused by B's decision not to seize.

Finally, the tampering itself will cause harm to society. We spend an incredible amount of money on the judicial system to ensure that justice is done. We are willing to pay, in the form of taxes, money to punish violators and receive the satisfaction of seeing them brought to justice. Tampering, whether A ultimately p.21 would have won or lost the condemnation suit, like corruption,

⁶³Please note that in my above discussion on inspections, see infra part B., when the expected punishment was lowered due to the time required to get a warrant, I only adjusted the magnitude of the actual punishment while keeping constant the probability that I would be convicted. Here, however, A's Expected Punishment is reduced because she is able to reduce the probability that she will be convicted even if she cannot lower the actual punishment if she is convicted. A more complex analysis might allow for both variables to be adjusted in each situation.

hurts the integrity of the system. Therefore, the Expected Tampering Harm, or (FT. is the expected harm caused to society caused by A's tampering, which is the product of the probability that A tampers and the actual harm T caused if A tampers. Let u be the probability that A tampers. Thus (FT = u~T.

In sum, the cost of not seizing is:

$$(1p)~(2EHc + R + (ET= (1p).s.H + R + u~T$$

As expressed earlier, the cost of seizing is:

$$E + p.q.D + (1-p).r.H$$

Therefore, seizing is efficient if the cost of seizing is less than the cost of not seizing, or if:

$$F + p.q.D + (1-p).r.H < (1-p).s.H + R + u~T.$$

Combining similar terms, seizure is efficient when:

$$E + p.q.D + (r-s)~(1-p)H < R + u~T$$

D.Criminal Sanctions

A third enforcement mechanism left to the FDA is criminal sanctions, which can be applied to either a company or an individual. This mechanism is a very powerful one since the FDCA 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....⁶⁴

While the Supreme Court has recognized that [h]ardship there doubtless may be under [this] statute, the Court found that in liblancing relative hardships,

⁶⁴U.S. v. Dotterweil 320 U.S. 277 (1943)(CB 1150, 1151).

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 before sharing in p. illicit commerce, rather than to throw the hazard on the innocent public who are wholly helpless.⁶⁵

There are two other aspects of the criminal sanction that are worth noting. The first is the guarantee exemption and the second is the causation requirement. Under §303(c) of the FDCA, a person who introduces an illegal article into commerce is [II] exempt from liability if he has received the article in good faith and obtained a written guaranty that it is not in violation of the Act.⁶⁶ Furthermore, since responsible corporate agents are held accountable only for causing violations of the FDCA, the Supreme Court has held that the FDCA permits the defendant, at trial, to raise a defense that he was powerless to prevent or correct the violation.⁶⁷ However, courts have defined powerless very narrowly.⁶⁸

There have been many efforts to relax the FDCA's strict criminal liability standard.⁶⁹ However, from an efficiency perspective, the strict liability standard, the guarantee exemption, and the causation requirement are all excellent devices and should not be changed.

The FDCA's strict liability standard is appropriate. Consumers are

⁶⁵*Id.* at 1152.

⁶⁶CBI165.

⁶⁷*U.S. v. Park* 421 U.S. 658 (1975)(CB 1155, 1158)(quoting *U.S. v. Wiesenfeld Warehouse Co.* 376 U.S. 86,91 (1964)).

⁶⁸In *Park*, 421 U.S. at CB 1155, 1156, the Court rejected defendant's powerlessness defense despite the defendant's claim that after delegating responsibility for corrective action to a division vice president, he did not 'believe there was anything Ihel could have done more constructively than what Ihel found was being done.' *Id.* (changes in original)

⁶⁹See Proposals to Change the Criminal Liability Standard 03 1163-64.

unable to reduce the chance of adulteration, filth or harms caused by deleterious substances. The people in responsible relation to the introduction of food and drugs into commerce are best able to detect and eliminate FDCA violations. They are the ones who are capable of preventing harms. If knowledge were a requirement for establishing criminal liability, then incentives to uncover a violation would be p.23 seriously jeopardized. Self-enforcement, which is essential considering the FDA's limited resources, would create knowledge, and thus, expose an individual or firm to liability. Self-enforcement, therefore, would disappear, and the phrase ignorance is bliss would be literally true in the food and drug industries. If, however, a CEO is exposed to possible criminal penalties if his company is introducing adulterated products into the market, that CEO is going to make sure that there are no violations. The strict liability standard greatly increases the incentives to avoid violations. Even a negligence standard would fail to preserve proper incentives. Under a negligence regime, the FDA would have to prove some level of fault. In many circumstances, this burden may be difficult meet. Therefore, strict liability is better. [T]he public interest in the purity of its food [and drugs] is so great as to warrant the imposition of the highest standard of care.⁷⁰

Furthermore, since it would be cheaper and easier for firms to determine the appropriate level of care than for courts to do so, strict liability is the best regime. Under a strict liability regime, courts do not have to determine due care levels. They can avoid this difficult task because firms are

⁷⁰Park 421 U.S. at CB 1155, 1157.

liable whether or not they had failed to take due care. Firms, however, will still determine optimal care levels under strict liability; they are required to pay for either the costs of taking care or the costs of not taking care; they will thus have the proper incentive to lower the total costs. Once again, strict liability is the proper standard.

The guarantee exemption is also efficient. Some companies, like the defendants in U.S. v. Balanced Foods, Inc.⁷¹ move thousands of goods into interstate commerce, goods that are produced, packaged, and labelled by other companies. If there were no guarantee exemption, then companies like the defendants in Balanced Foods would have to inspect every item themselves, submit samples of each product for testing, and expend enormous resources to avoid criminal liability.

Because the producers are the ones who truly control whether the products comply with the FDCA or violate it, and can ensure FDCA compliance at the cheapest cost, the guarantee clause is efficient.

Once again, a hypothetical can easily demonstrate this principle. Shipping company J transports all of producer K's medical devices. It costs J \$5 per device in shipping costs. If J could not get a guarantee to insulate itself from criminal liability, it would have to invest \$2 per device to insure compliance with the FDCA.⁷² J would, therefore, charge K \$7.25 per device to transport K's products (the \$0.25 represents economic profits). K makes the devices, however,

⁷¹146 F. Supp. 154 (S.D.N.Y. 1955)(CB 1166).

⁷²That \$2 would represent the firm's optimal investment in FDCA violation compliance. The firm would invest money in ensuring compliance until the cost of taking more care was greater than the benefit derived from such care (the benefit comes from the reduction in the expected criminal liability).

and thus K would only have to spend \$0.50 per device to achieve the same level of FDCA compliance that J achieved by spending \$2 per device. Furthermore, K already has to invest that \$0.50 to protect itself from criminal liability.⁷³ This duplicative effort is a complete waste of resources. Over-investment in compliance is just as inefficient as under-investment in compliance.⁷⁴ Furthermore, if J could get a guarantee which would protect it from liability, then it could charge \$5.75 for shipping K's products. J would be better off because it would make an extra \$0.50 per device in profits, and K would be better off because it would be paying J \$1.50 less per device in shipping costs without any additional costs of its own.⁷⁵ Furthermore, since these costs are always passed on to the consumer, in a regime with the guarantee exemption, the consumers would pay less for K's products. The guarantee clause avoids duplicative effort and creates a system where the cheapest complier takes sole responsibility for compliance. This result is optimal because it ensures the same, if not greater, level of compliance at a lower cost to everyone.⁷⁶

Finally, the causation requirement and the strict interpretation of

⁷³In reality, because K can ensure compliance at a lower cost, K would probably spend more than \$0.50 to ensure compliance and achieve a higher level of compliance than K would. As J did, K would invest in ensuring compliance until the cost of taking more care was greater than the benefit derived from such care. Different cost curves cause this difference in optimal levels of compliance.

⁷⁴See *supra* note 19. It would be foolish for J to spend \$10,000,000 and K to spend \$5,000,000 in efforts to comply with the FDCA when, alternatively, J and K can reach the same level of compliance if K spends \$5,000,000 and J spends \$100 to arrange for K to guarantee K's product. If J does not or can not get the guarantee, then \$9,999,900 has been wasted.

⁷⁵While realistically, there may be some transaction costs in drafting and obtaining a guarantee, once there was a standardized guarantee form, transaction costs should be negligible.

⁷⁶A greater level of compliance is possible because if K does not have to pay J the extra \$1.50, then transportation costs would be reduced, and there would be more money available for compliance efforts. Since K would not be diverting funds towards a duplicative effort, it can afford to spend more on compliance.

impossibility is efficient. If an individual truly did not cause the violation, had no ability to cure the violation, and was not responsible in any way for its introduction into commerce, then it is inefficient to punish that person. No deterrence can be achieved. Nothing can encourage people or firms to throw money away by trying to prevent violations they truly cannot prevent. Furthermore, the FDA will be wasting limited enforcement resources going after such individuals. Because the FDA's resources are so scarce, FDA should use its resources in a way which maximizes deterrence goals.

This argument, however, does not support a broad powerless defense. In U.S. v. Certified Grocers Co-Op⁷⁷ the defendant asserted an impossibility defense. The prosecution even stipulated that the defendant was doing everything possible to maintain sanitary conditions in the warehouse in question. The court refused to accept the defense, rightly reasoning that the defendant could have discontinued using the warehouse until the problem of rodent infestation had been solved. If courts did not hold defendants liable every time the defendants believed that they were doing everything possible, incentives would not be preserved. The threat of imprisonment is an incredible incentive to go that extra bit further, to find that impossible solution, or to simply close down a factory and accept a huge monetary p.26 loss until a solution can be found.⁷⁸

4.Recall

⁷⁷1968-1974 FDLI Jud. Rec. 299 (W.D. Wis. 1974)

⁷⁸I can't help thinking of a pop-culture analogy to illustrate this principle. I apologize in advance. In the movie Under Siege the head terrorist was played by Tommy Lee Jones. Tommy Lee Jones's computer systems expert was unable to regain control of a system. When this expert stated that regaining control was impossible, Tommy Lee Jones put a gun to the system expert's head. He then suggested that the punishment for failure was death. The systems expert remarkably found a way to do the impossible. Of course, all of the systems expert's efforts were wasted, because Steven Seagal. the hero, killed them all in the end.

Although there is some disagreement among different courts, and even among different Judges within the same court, courts have generally held that the FDA is powerless to request a judicially-enforced recall.⁷⁹ This result is problematic: [because FDA cannot enforce recalls, they are a matter of negotiation between industry and FDA and can be delayed or ineffectively carried out by the companies involved.⁸⁰ The General Accounting Office (GAO) found, by examining 106 recalls, that an average of 15 days passed before the firm acted on FDA's request for recall, 23 percent of the requests required 25 days for the companies to initiate recall.⁸¹ Furthermore, the GAO found that in those 23 percent of the cases, 38 percent of the product was sold during the delay.⁸² In one case, the firm took 55 days to initiate the recall, during which period, about 75,000 defective tablets were sold.⁸³ This situation is ridiculous.

The court in C.E.B. Products listed a number of reasons for its holding, including:

1)the FDCA doesn't provide for such authority;⁸⁴ 2) the threefold enforcement scheme of injunctions, seizure, and criminal prosecutions.... provides adequate before and after the fact remedies;⁸⁵ 3) recall would render the

⁷⁹See United States v. C.E.B. Products, Inc. 380 F. Supp. 664 (ND. II. 1974)(CB 1178); see also U.S. v. X-OTag Plus Tablets 441 F. Supp. 105 (D.Colo. 1977)(CB 1182. n.1), ~fLd 602 F.2d 1387(10th Cir. 1979). But see U.S. v. K-N Enterprises, Inc. 461 F. Supp. 988 (ND. II. 1978)(CB 1181).

⁸⁰GAO, Lack of Authority Limits Consumer Protection: Problems In Identifying and Removing From the Market Products Which Violate the Law Rpt. No. B-16 4031(2) (1972) (CB 1187).

⁸¹Id. at 1188.

⁸²Id.

⁸³Id.

⁸⁴C.E.B. Products CD at 1180-81.

⁸⁵Id. at 1180. See also U.S. v. Superpharm Corp., 530 F. Supp. 408 (E.D.N.Y. 1981)(CB 1183, n.1).

[defendant] company insolvent and necessitate bankruptcy proceedings;⁸⁶ and 4) [t]he injuries suffered by consumers, upon which proof was presentedónails splitting and falling off, redness, soreness, nail disfigurement, and infectionóalbeit serious and uncomfortable, are [in most cases treatable, and thus are] not of that severity and proportion to warrant the extraordinary remedy sought by the Government.⁸⁷

From a law and economics perspective, C.E.B. Products is an awful decision. Because courts refuse to order recalls at the FDA's request, one of these days, a real emergency is going to require a judicially-ordered recall, but the FDA will not pursue that avenue because they will not want to waste their limited resources on hopeless requestsóand the same scenario that resulted in the L-tryptophan tragedy will happen all over again. Each one of the court's reasons in C.E.B. Products for denying the power to request a judicially-enforced recall is misguided. First, whether the literal language of the FDCA permits recall is irrelevant. The only consideration is whether society is better off having recall or not having recall, or stated another way, whether the benefits to having recall outweigh the costs. If the language of a statute requires an inefficient result, the law should be changed either by Judges (through judicial fudging of the language of the statute)⁸⁸ or by Congress (through amendments). Realistically, there may be harms caused by judicial activism or administrative costs caused by the bureaucratic red tape required to amend a statute. And while such costs

⁸⁶C.E.B. Products CB at 1180-81.

⁸⁷Id. at 1181.

⁸⁸See U.S. v. K-N Enterprises CB at 1181.

might outweigh the benefits gained by permitting the efficient result,⁸⁹ such considerations are the subject of another paper. For purposes of this paper, if we are better off having recall in the long run as a judicially-enforceable remedy, then we should have it.

Second, the fact that the FDA's powers of injunction, seizure, and criminal prosecutions are adequate is not a justification for not allowing a judicially-enforced recall. The only relevant consideration is whether society is better off having court-ordered recalls or not having them. While the other options may be adequate, recall in certain circumstances is better than adequate. Product recall has evolved over the years as the most expeditious and effective method of removing violative products from the marketplace, particularly those that present a danger to health.⁹⁰

If the court's real concern is that the FDA would be too powerful, that recall is so potentially devastating that the FDA cannot use it effectively, then that at least would be looking at an appropriate concern. However, since voluntary recall is common, it seems clear that the FDA can handle the power. More importantly, the court must order the recall; therefore, the court can review the FDA's request to prevent abuses of discretion. Finally, §705 of the FDCA expressly authorizes the issuance of information to the public.⁹¹

⁸⁹If the lack of recall authority costs this society \$100,000 per year (the benefits to having such a power would outweighs the costs by this amount), but the administrative costs involved in amending the statute was \$10,000,000, then the cost to society in changing the system would be greater than the net present value of the benefit gained by changing the system. It would, therefore, be inefficient to change the system, and thus, mandatory recall would not be worth the cost of getting it.

⁹⁰Enforcement Policy. Practices and Procedures: Recall Policy and Procedures 41 Fed.Reg. 26924 (June30, 1976).

⁹¹Arthur Kallet & F.J. Schlink, 100.000.000 Guinea Pigs (1933)(CB 1194, 1195).

This dreaded power of publicity is the real punishment⁹² which could destroy a company a lot more effectively, and a lot more inexpensively than getting a court-ordered recall. If we were really that concerned about FDA abuses of discretion, then an issuance of publicity would have to be reviewed by the court. If court-ordered recall is the most effective remedy in p.29 certain instances, then the fact that there are other, less-efficient, but adequate, substitute remedies is not a valid reason for withholding this enforcement device.

Third, the argument that recall could bankrupt a company facing such a contingency is not a justification for denying such authority. The company in question should have thought of that contingency before it allowed a dangerous substance on the market. If a company chose to take the risk of putting such a product on the market, it should bear the loss of such a decision. Otherwise, companies will have the incentive to take dangerous risks because courts are unwilling to bankrupt them; therefore, the companies will not have to factor those costs into their decisions and will not behave optimally.

Moreover, if mandatory recall became common, recall insurance could become available. There would be many advantages to such insurance. Ideally, insurance companies set premiums at the Expected Cost, or (EC of insuring each of its clients. Let q be the probability that Insurance Company I will have to pay a claim for its insured X .⁹³ Let C be the actual cost of paying the claim if there is a claim. Therefore, the optimal premium P for I's coverage of X would equal the probability of a claim multiplied by the cost of paying the

⁹²Id. at 1194.

⁹³The claim in this case is one for reimbursement of expenses incurred in X having to recall a product

claim, or: $P = (EC = q.C$.

Now let's look specifically at recall insurance. The benefit of each insured paying P rather than a q chance of paying C is twofold: 1) risk is spread among many parties; and 2) the assets required for each company to optimally internalize costs will be reduced. A hypothetical will demonstrate these two principles. Assume that there are 100,000 companies, each with one product that falls within the FDA's jurisdiction. Now assume that each year there are 10 recalls. Also assume that insurance companies would not be able to determine which types of companies were more at risk from recall.⁹⁴ Assume that if a recall is ordered, it will cost p.30

\$10,000,000. The probability that company X will have to recall it's product in any one year is 10 in 100,000 or 0.01 percent, so $q = .0001$. Therefore, since $P = (EC = q.C$, $P = 0.0001\$10,000,000 = \$1,000$. If manufacturers are risk averse, then by definition, they would prefer to pay the \$1,000 and avoid the possibility of a devastating \$10,000,000 loss. Recall insurance, like tort insurance, or disaster insurance, would spread great risks over a large group of people. Spreading risk makes risk averse parties better off, therefore, it is socially advantageous.⁹⁵ Furthermore, there would be little dissolution of risks. Insurance companies could monitor care and preserve incentives by adjusting the premiums for higher risk insureds, denying coverage in certain instances, or

⁹⁴In an actual insurance system, I would develop actuarial tables and would more accurately set risk levels, i.e., the probability of paying a claim q (for example, a person who has been in five car accidents in the last year would almost certainly pay a higher auto insurance premium than someone who has never been in an accident in 25 years of driving; similarly, people who live in a New York City pay a higher premium for auto theft insurance than people in areas where motor vehicle theft is rare).

⁹⁵See Shavell, Principles of Economic Analysis of Law §17.1. In the case of recall, since recall is a fairly rare occurrence, premiums for recall insurance should be relatively reasonable.

employing the use of deductibles.⁹⁶ If insurance greatly decreased incentives to take care, then many accidents, or in this case, recalls, would occur. If a great number of recalls would occur, then the expected costs that insurance companies would have to pay to insure the firms would greatly increase. The insurers would have to increase premiums so much that it would not be worthwhile for insurance to continue. [Policies that would substantially increase risks would be so expensive that they would not be attractive for purchase.⁹⁷

Additionally, an argument can be made that incentives to take care under an insurance regime will be greater than in a regime without insurance. Without insurance, if a company would be bankrupted by a recall, the company's total assets would be less than the cost of a recall. Since that company can at most spend its total assets,⁹⁸ it only has to factor its total assets into its decisions to take care, and does not have to factor in the true cost of recall. This is because the true cost of recall is more than it would or could ever have to pay. Going back to the hypothetical where $q = .0001$ and $C = \$10,000,000$, assume X only has \$1,000,000 in assets. If X had an insurance policy covering recall, and the policy accurately reflected risk, the premium would always be set to reflect the Expected Cost of Recall, or (EC = \$1,000. Because the firm has \$1,000,000, it could afford the premium. Under an insurance regime, therefore, an insured is only paying for expected recall costs, and thus, the insured is internalizing the entire cost of recall. In a non-insurance regime, if a recall would

⁹⁶See Shavell, Principles of Economic Analysis of Law §17.

⁹⁷Shavell, Principles of Economic Analysis of Law §17.4.4.

⁹⁸Assume that because of its poor financial situation, the company could not borrow additional funds. If it could borrow additional funds to cover the cost of recall, the recall would not bankrupt the company.

cost \$10,000,000, the firm could at most be forced to pay \$1,000,000. If a firm were forced to recall, then q would stay at 0.0001 but C_x would be \$1,000,000 which is the total cost X would pay for recall (their total level of assets). Therefore, the Expected Cost of Recall for X would only equal $q.C_x = \$100$, when it should truly be \$1,000. Therefore, when choosing care levels to avoid recalls, under a system without insurance, a firm with limited assets would not fully internalize all the costs involved, but would only internalize the costs it could bear.⁹⁹ An insurance regime, in which premiums are set at the expected cost to society, would better preserve incentives to take care when companies could not afford to bear the full cost of a recall.

The final justification of the court in C.E.B. Products was that recall was not warranted since the harm caused by the product was not severe. While weighing the harm caused by the product, or better yet, the harm prevented by the recall is a crucial determinant in whether a recall is efficient, it is not the only consideration. The court should have determined whether the cost of a recall was cheaper than the harm avoided. For example, in U.S. v. K-N Enterprises Inc.¹⁰⁰ the court properly ordered recall after finding that [t]he damage possibly sustained by the defendants p.32 because of an improper recall is outweighed by th[e] threatened harm and by the undisputed violation[s of the FDCA].¹⁰¹

A recall is efficient when the benefits to recall outweigh the costs,

⁹⁹For a further discussion, see Shavell, Principles of Economic Analysis of Law §15.8.

¹⁰⁰461 F. Supp. 988 (N.D. II. 1978)(CB 1181)

¹⁰¹Id. at 1182.

i.e., when the harm avoided by a recall outweighs the costs involved in recalling the product. Assuming the FDA, in its discretion, could use mandatory recall efficiently, this power should be granted. As the GAO stated, in certain instances, recall is the most expeditious and effective method of protecting the public. Therefore, in these instances, recall avoids more harm to society than it costs.

If manufacturers were held to a perfect strict liability standard, where they were required to pay for all the harms to society, then they would always act in a socially optimal manner.¹⁰² In this regime, a firm would want to recall the products whenever it would be socially efficient to do so because it would be cheaper than paying for all the injuries or damage to society. Let S be the cost to society if recall were not used in this situation. Let F be the cost the firm would face if recall were not used. Let R be the cost of a recall. If a recall is socially efficient then $S > R$. But if a firm refused to order a recall when a recall were socially efficient,¹⁰³ then the costs to the firm of recalling would be greater than the cost of not recalling, or $R > F$. Therefore, $S > R > F$. This demonstration proves that any time a firm refuses to order an socially efficient recall, the cost the firm would pay if it did not order the recall is less than the cost that society would pay if the firm did not order recall. The firm, by definition, would not be internalizing all costs to society caused by its action.¹⁰⁴ Whatever the reason for this failure, the firm's costs fail to adequately reflect all the costs to society,

¹⁰²See *supra* note 11 and accompanying text.

¹⁰³I am assuming there is no uncertainty as to whether a recall is efficient.

¹⁰⁴See *infra* part A.

and therefore, the firm is not acting in a socially optimal manner. Firms should not be allowed to refuse to institute a socially efficient recall. Rather, the FDA should be given the power to request a judicially p.33 enforced recall.

Conclusion

Many of the types of issues and considerations discussed in this paper can be applied to other areas within the field of Food and Drug Law. For example, the entire regulatory scheme for drugs needs to be analyzed. Is pre-market approval of all new drugs cost efficient? Are incentives to discover or create new drugs destroyed under the current regime? Should patients with terminal illnesses be allowed to use new, unapproved drugs? In what circumstances? In the field of cosmetics, should there be more stringent regulatory requirements? Or would the costs to new regulation outweigh any benefits? These are only a sample of the many areas in which Law & Economics will be useful. And while I may not have left the reader with many answers, hopefully, I have left him or her with many questions, and a framework for thinking about those questions.