PRECIOUS PRODUCT POISONING:

Legal and Public Relations Issues

Julie Wang

St. Cloud State University, MBA 612

April 28, 2019

Precious Product Poisoning: Legal and Public Relations Issues

INTRODUCTION

What would you do if your company sold pet food that would potentially kill the very animals it was meant to feed? Would you immediately alert everyone or try to hide it? Those are some questions the president of Precious Product Corporation ("Precious Products") must answer. In the following scenario, the company's president became aware of questionable actions taken by new hires. Specifically:

> You are the President of Precious Product Corporation. You have just become aware that entry-level employees have been mixing unapproved protein supplements into the MASTER MIX for your main product, a universal pet food. The master mix is the basic supplement utilized as an ingredient in all pet foods given to ***any*** mammal. Unfortunately, while these unapproved protein supplements mimic the effect of natural protein, they do not have any nutritional value and prolonged use of the supplements eventually cause kidney failure followed by the death of the mammal. No one told the new hires to do this, nor did anyone in the company condone this behavior; in fact, the supervisor told the new hires to STOP this activity as soon as she heard what was going on. The rest of the board has told you to forget about it. What do you do?

In order to decide how to best handle the situation, the president needs to consider legal, ethical, and moral standards. He needs to determine which laws have already been broken, and which laws could still be broken. Laws relating to torts, crimes, contracts, the UCC, and FDA regulations need to be analyzed. The president also needs to decide whether to terminate employees or supervisors; whether to alert authorities; and whether to alert the press. Finally, the president is in the precarious situation of reporting to a board of directors that seems keen on committing negligence, fraud, and product liability. How can the president legally handle the board, considering his duties as an officer and agent of the company? The president needs to determine and weigh his options in light of legal, ethical, and moral standards.

LEGAL, ETHICAL, AND MORAL STANDPOINTS

Legal standpoint. The most significant legal issues surrounding this case are those of employment law, contract law (in terms of duties of officers and agents), breach of nonconforming goods, breach of warranty, consumer laws, various FDA regulations, fraudulent misrepresentation, negligence, strict liability, corporate criminal liability, and product liability. The president needs to determine and consider which laws have already been broken; how to

avoid breaking more laws by taking corrective action; whether his actions violates any of his duties as an officer and agent; and whether he violates any employment laws when dealing with the employees and supervisors.

Ethical standards. The president also needs to consider which business decisions are ethical, as well as his own personal moral values. The two terms are very similar, but *ethics* refers to a broader set of rules, actions, or behaviors, while *morals* refers to individual principles. “A *moral precept* is an idea or opinion that’s driven by a desire to be good. An *ethical code* is a set of rules that defines allowable actions or correct behavior.” (Dictionary.com, 2019.) Precious Products likely has its own code of business ethics, as most companies do. Such ethics might include being socially responsible; providing safe products to consumers; and being honest. If the president decides to ignore the problem of adulterated products, this would violate all those ethical standards; recalling the products as soon as possible is the ethical (and legal) thing to do.

It is important to note that laws are closely related to ethics, because they both focus on “social beliefs about right and wrong behavior in the business world” (Clarkson, pg. 111). The law "does not and cannot" lay out every ethical issue, but the law *assumes* that businesses are acting ethically. "If they do not [act ethically], the courts will not come to their assistance." (Clarkson, pg. 111.) This is a good explanation of the relationship between law and ethics. Generally, ethical standards are broader than laws, and even when something is not technically illegal, it may still be unethical, and the offending party could still be found guilty in the court.

Moral standards. With regard to the president’s individual moral values, he needs to look to his own belief system. Many people would agree that it is wrong to harm or kill animals; knowing that humans could potentially get sick or die from the adulterated products should be even more worrisome. Many people believe in the ten commandments of the Bible, particularly “Thou shall not kill.” If the president believes this, then the potential for humans to die should be enough for him to take appropriate action in this situation.

APPLICABLE LAWS AND APPLICATION

The first issue at hand is whether laws were broken when the new hires added unapproved protein supplements to the Master Mix. Regarding tort law, Precious Products would likely not be required to pay damages because no harm or loss has yet occurred. However, various contract laws, consumer laws, and FDA regulations have already been broken.

Torts and Crimes. Tort law has to do with compensating those who suffered harm or loss caused by the wrongful acts of another person, whether intentional or not. Torts can be against people or property. Compensation, or damages, can be in the form of compensatory (i.e. monetary), equitable (e.g. performance), or punitive (i.e. punishing) damages. Several torts are applicable in the case study of Precious Products, including fraudulent misrepresentation, negligence, strict liability and corporate criminal liability.

i) *Fraudulent misrepresentation*. Fraudulent misrepresentation, or fraud, involves: knowingly misrepresenting material facts; an intent to induce another to rely on that misrepresentation; an actual reliance on the false information by the deceived person; damages suffered; and a causal connection between the false information and the losses suffered. (Clarkson, pg. 123, 277.) Furthermore, misrepresentation can occur by a specific action or by silence. If action is taken by a seller to conceal a material fact, such action would be considered misrepresentation by conduct. If a seller is silent about material facts, that silence could also be considered misrepresentation. While neither party to a contract is obligated to disclose *all* the facts, a seller is obligated to disclose non-obvious defects. (Clarkson, pg. 278.) Should Precious Products fail to disclose to its consumers that the products have been adulterated, and consumers suffer harm or loss because of that adulteration, Precious Products would be guilty of fraud.

ii) *Negligence*. Negligence is a type of tort in which someone suffered loss or harm "due to another's failure to live up to a required duty of care." Duty of care is based on the expectation that people's actions should not harm others, and that people will take reasonable care not to do so. In order to prove negligence, the plaintiff must show that the defendant had a duty of care; that the duty of care was breached; the breach caused some form of harm; and the harm was a legally recognizable injury (Clarkson, Pg. 136). If the defendant "intentionally failed to perform a duty with reckless regard of the consequence to others," this would be considered gross negligence (Clarkson, pg. 141). If Precious Products did not (and does not) exercise reasonable care to keep its consumers safe, and consumers suffer harm because of that lack of care, then Precious Products will be found guilty of negligence.

iii) *Strict liability*. Whereas negligence involves causing harm by not following a duty of care, strict liability means causing harm *despite* using the utmost care. An important type of strict liability is product liability, which is the liability of manufacturers for harmful or defective products. Product liability is based on two factors: "1) the manufacturing company is in a better

position to bear the cost of injury because it can spread the cost throughout society by increasing the price, and 2) the company is making a profit from its activities, and therefore should bear the cost of injury as an operating expense" (Clarkson, pg. 147). Even if precious products used the utmost care in production, it should still carry the burden and expense of correcting the problem of harmful or defective products. If it does not, and harm is suffered as a result, then Precious Products would be guilty of product liability.

iv) *Corporate criminal liability*. Criminal liability has to do with crimes against society as a whole, and involves both a harmful act and an intent (Clarkson, pg. 174). Two types of criminal law may apply in the case of Precious Products: criminal negligence and corporate criminal liability. Criminal negligence involves taking an "unjustified, substantial, and foreseeable risk that resulted in harm" (Clarkson, pg. 177). In other words, being reckless. Corporate criminal liability involves a corporation's harmful acts that could have been prevented. A corporation can be found guilty of criminal liability by the actions of its agents, including directors, officers, and employees. In order to establish a corporate criminal liability case, prosecutors should be able to prove "that the corporation could have prevented the act or that there was authorized consent to, or knowledge of, the act by persons in supervisory positions within the corporation." Additionally, corporations can be found guilty for failing to follow federal regulations, such as environmental or securities laws. (Clarkson, pg. 177-178). We don't know the details of why or how the protein supplements were added to Precious Products' Master Mix. It could have been due to recklessly risky operations (e.g. no labeling, no quality inspections). Nevertheless, it probably could have been prevented, and at a minimum, Precious Products failed to follow various FDA regulations. If harm is suffered, Precious Products could be found guilty of corporate criminal liability.

As described above, tort law has to do with compensating those who suffered some form of harm or loss due to wrongful acts of another person. In the case of Precious Products, no harm or loss has occurred – yet. Therefore, the tort laws described above (i.e. fraudulent misrepresentation, negligence, strict liability, or corporate criminal liability) would not apply at this point, because no harm has been done. Should the company decide *not* to recall the products, then the likelihood of harm or loss greatly increases, and the company would likely be found guilty on all accounts. Furthermore, with respect to ethical standards, the company and its agents should *want* to prevent any harm or loss from occurring. The company should strive to provide

safe products, and if a product is found to be unsafe, the company should do everything in its power to remove that product from the market and from consumers, regardless the cost.

Contracts and the UCC. Contract law, especially the Uniform Commercial Code, is particularly relevant in the case of Precious Products. A valid contract includes: an agreement (i.e. an offer and acceptance); consideration (i.e. something of value is exchanged); contractual capacity (i.e. both parties must be competent); and legality (i.e. the goal must be legal) (Clarkson, pg. 208). Contract law can be based on either common law (e.g. for services, real estate, employment, or insurance) or statutory law (e.g. the UCC for sale or lease of goods). If the UCC addresses a specific issue, the UCC rule will govern; if the UCC is silent over a specific issue, then common law will govern (Clarkson, pg. 357). Either party can be found guilty of breach of contract for a multitude of reasons, and various types of damages can be awarded. In the case of sales contracts, the UCC addresses many such breaches and damages. Several UCC laws are relevant in the case of Precious Products, including: breach of contract with nonconforming goods; breach of warranties; and product liability.

i) *Breach of contract for delivering nonconforming goods*. Under the UCC, parties are expected to act in "good faith," defined as "honesty in fact and the observance of reasonable commercial standards of fair dealing in the trade" (Clarkson, pg. 363; UCC 2-103(i)(b)). Merchants (i.e. sellers) are held to a higher standard of performance than are non-merchants, and are basically obligated to deliver *conforming* goods, or goods that are "in accordance with the obligations under the contract" (UCC 2-106(2); Clarkson, pg. 401). To determine whether the goods are nonconforming, courts may refer to the "perfect tender rule," which states that "if goods or tender of delivery fails *in any respect* to conform to the contract, the buyer has the right to reject them" (UCC 2A-509(1)). The risk of loss does not pass to the buyer until defects are cured (e.g. repaired, replaced, or discounted) or until the buyer accepts the goods in spite of defects (Clarkson, pg. 396). If the buyer accepts the goods, then later discovers the nonconformity (either because it was non-obvious or because the seller assured the buyer that the goods were conforming), and if the nonconformity substantially impairs the goods' value, then acceptance of the goods can be revoked (Clarkson, pg. 414). Both conditions need to occur. Precious Products is already guilty of breach of contract for delivering nonconforming goods. Assuming that customers bought pet food believing it to be safe, and later discovers the food contains a new, unlabeled ingredient that could kill the pet, the owner could revoke its

acceptance of the product and sue the company for breach of contract for delivering nonconforming goods.

ii) *Breach of warranties*. The UCC addresses both express warranties and implied warranties. An express warranty is created when the seller makes an "affirmation of fact or promise" relating to the goods, and that the goods will conform to that promise (Clarkson, pg. 422; UCC 2-313). No formal language is required, just reasonable representation, and the representation only applies to statements of fact, not opinions. An implied warranty is created any time something is sold by a merchant who ordinarily deals in goods of that kind (Clarkson, pg. 423; UCC 2-314, 2-315). For example, a pet food company makes an implied warranty of *merchantability* every time it sells pet food products. To be merchantable means to be "fit for the ordinary purposes for which such goods are used" (UCC 2-314(2)(c); Clarkson, pg. 423). They must be "adequately contained, packaged and labeled" and "conform to the promises … of fact made on the container or label" (UCC 2-314(2)(e-f)). Even if the seller was not aware of a nonconforming defect, the seller could still be held liable for the defect (Clarkson, pg. 424). An implied warranty of merchantability is created when Precious Products sold pet food containing the Master Mix. In other words, the company promised to sell pet food that is merchantable, i.e. fit for feeding pets. Undeniably, pet food that is potentially fatal to the pets when consumed is *not* merchantable. Therefore, pet food that was sold even prior to discovering the added protein supplement would be a breach of warranty.

iii) *Product liability*. Product liability is an important element of the Precious Products case. As discussed under tort law, when a product is sold that causes physical harm or damage to the consumer, the seller can be held liable. Product liability can be based on breach of warranties, negligence, fraudulent misrepresentation, or strict liability. (Clarkson, pg. 429-430). Under breach of warranty, the seller delivers a nonconforming product; Precious Products is already guilty of this. Under negligence, a manufacturer fails to exercise due care to make a product safe. Specifically, the manufacturer should exercise due care in product design, material selection, production process, assembly, testing and inspection, and labeling. Precious Products is already guilty of failing to exercise proper due care. With regard to fraudulent misrepresentation, the seller intentionally mislabels material facts (e.g. product defects) about the product, either knowingly or with reckless disregard for the facts. Precious Products is assumed *not* to have added the dangerous protein supplement to the product labels, and therefore is

already guilty of fraud. Last, in a strict product liability case, six requirements must be met: the product is defective when sold; the seller normally engages in the business of selling that product; the product must be unreasonably dangerous to the consumer; the consumer must have incurred harm or loss; the defective condition must be the cause of harm; and the product was not changed form time of sale to when injury was sustained (Clarkson, pg. 430). Product defects could be due to manufacturing defects, design defects, or inadequate warnings (pg. 431). The product may have been incorrectly assembled, and/or the seller may not have imposed adequate inspections of the product quality.

With respect to Precious Products and product liability, as with torts, harm or loss must be present in order for a plaintiff to collect damages. Therefore, product liability would not apply – yet. If Precious Products decides not to recall the products, then in all likelihood pets would start getting sick and dying, after which Precious Products would be also be found guilty of product liability. Again, ethically, Precious Products should endeavor to do everything in its power to provide safe products to consumers, to avoid any such damage. Just because no harm or loss has yet been suffered does not mean that Precious Products should not take ethical action.

Consumer Laws. Consumer laws aim to protect consumers from problematic sales and transactions, such as "unfair trade practices, unsafe products, discriminatory or unreasonable credit requirements" (Clarkson, pg. 880). Furthermore, the Fair Packaging and Labeling Act of 1966, among others, address problems of deceptive advertising, labeling and packaging (Clarkson, pg. 884-885). Food labeling is relevant in the case of Precious Products, since the protein supplements presumably were not added to the labels. Additionally, the label likely was not modified to include a warning that the product is potentially fatal if consumed over time.

Furthermore, The Consumer Product Safety Act of 1972 requires that distributors of consumer products notify the CPSC immediately if they receive information that a product "contains a defect which … creates a substantial risk to the public" or "an unreasonable risk of serious injury or death" (Clarkson, pg. 895). Precious Products still has a chance to fulfill this requirement by recalling the adulterated products, but they must do so immediately.

Food and Drug Administration. The Food and Drug Administration ("FDA"), an agency of the U.S. Department of Health and Human Services, is the primary regulatory authority for the pet food industry. Basic food laws fall under the Federal Food, Drug, and Cosmetic Act ("FD&C"). The Code of Federal Regulations ("CFR"), Title 21, Chapter I,

Subchapter E (parts 500-589) also cover regulations relating to animal drugs, feeds, and related products. The FDA Food Safety Modernization Act ("FSMA") of 2011 provides the most updated pet food regulations, which focuses on preventing contamination rather than reacting to contamination. In addition to FSMA requirements, pet food manufacturers are encouraged to follow the guidelines set forth in Current Good Manufacturing Practice Requirements for Food for Animals ("CGMPR") of 2017.

In the case of Precious Products, applicable FDA regulations likely include the following:

1) Food for animals does not need FDA's pre-market review to be marketed, but the FD&C requires pet food to be safe, made under sanitary conditions, free of harmful substances (especially additives), and truthfully labeled (*FDA Regulation of Pet Food*). Again, the protein supplement made the Precious Products pet food unsafe and would not have been added to the labels; both acts are in violation of these standards.

2) All ingredients need to be listed on pet food labels, in order of predominance (*FDA Pet Food Labels – General; 21 CFR §501.4*). Certain exemptions may apply for small entities. It is assumed that Precious Products Corporation is *not* considered a small entity, and therefore is not exempt from any FDA regulations. Again, it is assumed that the protein supplements were not added to product labels, which is in violation of this rule.

3) It is illegal to use an unapproved food additive [as opposed to supplement] in pet food (*FDA Regulation of Pet Food*). It is assumed that the protein supplement added to the Master Mix is *not* considered an unapproved food "additive."

4) The Dietary Supplement Health and Education Act ("DSHEA") does not apply to animal food (*Federal Register, 1996*). This indicates that the protein supplements added to the Master Mix animal food are not regulated by the FDA in the same way as food supplements added to human food. Therefore, the FDA regulations on human food supplements do not apply in this case. However, it is important to consider that the Master Mix could potentially make its way into human beings, either by way of the Master Mix being fed to animals produced for human consumption or by humans consuming pet food directly for some reason, such as by young children or by those consuming pet foods due to financially desperate situations. The possibility of this situation adds another layer of legal, ethical, and moral considerations. Specifically, if any agents of the company believe it wrong to poison people, they should do everything in their power to remove the unsafe, unlabeled products from people's hands.

5) Per 21 CFR §507.4(a), management is required to "ensure that all individuals who manufacture, process, pack or hold animal food … are qualified to perform their assigned duties." Similarly, 21 CFR §507.4(b) requires that each person manufacturing, processing, packing, or holding animal food must be qualified to do so in terms of education, training, or experience, and must receive training as appropriate to the animal food, the facility, and the individual's assigned roles. Moreover, supervisory personnel are responsible for ensuring compliance, and must keep records of the employees training (21 CFR §507.4(c-d)). These regulations will come into play when the president of Precious Products considers whether to terminate the new hires and/or the supervisor.

6) Per 21 CFR §507.25(a), management must ensure compliance with Current Good Manufacturing Practice Requirements (CGMPR), specifically that "all operations in the manufacturing, processing, packing, and holding of animal food (including operations directed to receiving, inspecting, transporting, and segregating)" comply with CGMPR standards. Such requirements include (but are not limited to):

a. All raw materials need to be accurately identified (21 CFR §507.25(a)(2)) – which the protein supplements presumably were *not* identified at Precious Products;

b. Precautions must be taken so that plant operations do not contribute to contamination of animal food (21 CFR §507.25(a)(5)) – which Precious Products evidently failed to do, because in order for the protein supplements to make their way into pet food products and get sold and distributed, there must have been a gap in operations procedures;

c. Chemical, microbial, or extraneous-material testing procedures are used to identify sanitation failures or possible animal food contamination (21 CFR §507.25(a)(6)) – evidently, Precious Products did not have adequate testing procedures in place to immediately identify and prevent the animal food contamination;

d. Animal food that has become adulterated (i.e. to render something poorer in quality by adding another substance) must be rejected, disposed of, or processed to eliminate the adulteration (21 CFR §507.25(a)(7)) – Precious Products has yet to do this; and

e. Animal food companies must implement a hazard analysis, which includes identification and evaluation of any known *or reasonably foreseeable hazards* for each type of animal food manufactured, to determine whether any hazards require a preventive control (21 CFR §507.33). Furthermore, if a preventive control was required, then 21 CFR §507.34 and

507.38 would apply, which requires animal food companies to implement a recall plan, which involves notifying customers and the public of the hazard and how to return the contaminated food, and ensuring the recall plan is carried out.

Clearly, Precious Products failed to comply with several FDA regulations, as described above. One FDA regulation that has yet to be followed is that of 21 CFR §507.25(a)(7), which states that animal food that has become adulterated must be rejected, disposed of, or processed to eliminate the adulteration. Precious Products still has a chance to follow this regulation with a recall; if they fail to do so, then that will be yet one more law broken.

Additionally, 21 CFR §507.33 requires animal food companies to implement a hazard analysis, which includes identification of any known or reasonably foreseeable hazards. If such foreseeable hazards are identified, then a preventive control is required. The question remains whether new hires adding new ingredients to the Master Mix was foreseeable. This is debatable, but one could argue that new hires erroneously mixing in the wrong ingredients is a foreseeable event, especially if the wrong ingredient was made readily available to the new hires. For this reason, it is concluded that Precious Products Corporation would probably require a preventive control, which would call for hazard controls and written recall plans. Even if a preventive control were not required, 21 CFR §507.50 requires that "whenever a significant change in the activities conducted at your facility creates a reasonable potential for a new hazard or creates a significant increase in a previously identified hazard, then the company must conduct a reanalysis of the food safety plan as a whole." In other words, once the company became aware of a potentially hazardous material being added to the product, this should trigger a reanalysis of the food safety plan, which would likely identify the hazard of the protein supplement, which would likely trigger a recall. If Precious Products fails to do this, then yet another law will have been broken.

Case law. Case law sets a precedent which courts can follow in other similar cases. A relevant case includes that of Toyota Motor Corporation ("Toyota"), in which the Justice Department brought a criminal charge against Toyota for concealing pertinent information and making deceptive and misleading statements about safety issues affecting its vehicles (U.S. Department of Justice, 2014). While automobile safety and pet food manufacturing are completely different industries, the case of Precious Products are similar in the fact pattern in that both companies became aware of defective products that pose a danger to consumers. The

Toyota case provides Precious Products with a good example of how to respond, and what *not* to do. The key issues included:

1) Toyota became aware of the problem, but they did not inform U.S. regulators of the problem or conduct a recall. Instead, they *quietly* changed the pedals in Europe, and made plans to do the same in U.S.

2) Toyota hid the problem from the public. They planned to correct the problem without leaving a paper trail; the corrective work was to be done verbally, in order to prevent U.S. regulatory (NHTSA) from discovering the problem.

3) Toyota made misleading statements. They minimized the issue to the public, and the company did not adequately address the problem by way of a recall.

4) Toyota gave a false timeline. They tried to make it look like the company just learned about the problem within the last 90 days, when in reality they had learned about it months prior.

Toyota was found guilty of defrauding consumers and issuing misleading statements about safety issues. Toyota paid a $1.2 billion penalty to avoid prosecution from the Justice Department (for defective floor mats and sticky pedals). Attorney general Eric Holder summarized Toyota's wrongful acts as follows: "Rather than promptly disclosing and correcting safety issues about which they were aware, Toyota made misleading public statements to consumers and gave inaccurate facts to Members of Congress." Furthermore, U.S. Attorney Preet Bharara explains: "Toyota stands charged with a criminal offense because it cared more about savings than safety and more about its own brand and bottom line than the truth."

This Toyota case sets a precedent, and the takeaway is that Precious Products should notify authorities, issue a voluntary recall, and do it quickly. While the Toyota example is dealing with human lives rather than pets, and vehicles rather than pet food, the key issues of knowingly selling faulty, nonconforming, unsafe products seem the same. Once pets start dying and the problem is traced back to Precious Products, the company (and its officers) will be in dire straits, and most definitely found guilty of fraud, misrepresentation, negligence, criminal liability, and product liability, etc. Obviously, the company should issue the recall for legal reasons, but for ethical reasons as well; Precious Products should care more about the safety of consumers and being honest than its own bottom line. Courts would likely agree, as shown in this Toyota case.

Another previous case relevant to that of Precious Products has to do with one of the largest pet food recalls in history (In re Pet Food Products Liability Litigation, No. 08-4741, 3rd Cir. 2010). In this case, over 180 brands of pet food and treats produced by 12 manufacturers were recalled due to imported ingredients contaminated with melamine and cyanuric acid, resulting in sickness or death of thousands of pets. Plaintiffs alleged violations of state consumer protection and deceptive trade practice statutes, along with claims for product liability, breach of warranty, and negligence. One of the allegations was that pet food manufacturers mislabeled their products by indicating "Made in the U.S.A." when in fact ingredients were imported from China. The District Court agreed to a settlement of $24 million. (In re: Pet Food Products Liability Litig., 08-4741 (3rd Cir. 2010).) This case sets precedent in the importance of proper labeling as well as delivering safe products. Failure to do so would make a manufacturer guilty of product liability, breach of warranty, and negligence, as decided in this case.

WHETHER TO FIRE NEW EMPLOYEES AND/OR SUPERVISOR

Whether to fire new employees. Assuming the new employees were adequately trained according to the provisions under 21 CFR §507.4(a), they should probably be fired. If the employees go through training and learn the importance of safety, labeling, operations, and federal regulations, then it is assumed that the employees would know and understand the consequences of adding potentially dangerous ingredients to pet food. In fact, any alteration to any pet food product would need to follow strict approval and protocol, whether it is potentially dangerous or not. It can be argued that new employees in general should have had the common sense to at least check with a supervisor before altering any product. Last, the case states that the supervisor told the employees to stop adding the ingredient immediately. We don't know whether the employees complied; if they did not, that is even more justification for termination.

If the employees were not adequately trained, or if proper procedures were not in place to prevent the wrong ingredients from being mixed into the products, then the company has more serious problems to resolve. Lack of training and safe, sanitary operations would violate various FDA regulations described above. If the employees were not sufficiently trained, then the company may consider putting them on a probationary period and putting them through extensive training, and instead consider terminating the supervisor.

Whether to fire the supervisor. The key determinant in whether to terminate the supervisor is whether the supervisor exercised due care. If the supervisor made sure employees were well-trained, that operations ran smoothly, and that an abundance of quality checks and inspections were being done, then there is no apparent reason to terminate the supervisor. On the other hand, if training was inadequate, operations were spotty, and quality checks were lacking, then the supervisor should be terminated. Evidently, in the case of Precious Products, operations were somehow violated. Where did things go wrong? Were raw ingredients not separated and labeled? Where did the new hires get the protein supplements? Were quality inspections done? We do not have enough facts to allow us to make an informed decision. For all we know, it could have been during the supervisor's impeccable inspections that the adulteration was identified. On the other hand, maybe there were no inspections. The protein supplements may have only been added for a period of 2 hours or 2 days, or they may have been added over a period of 2 months or even 2 years. We don't know the facts, so the question of whether to terminate the supervisor is difficult to answer. Until a lack of due care is found, the supervisor need not be terminated.

Consider employment laws. One last consideration is whether terminating either employees would violate any employment, immigration, or labor laws. For example, it is illegal to discriminate against workers from a protected class, i.e. based on race, color, religion, national origin, gender, age, or disability (Clarkson, pg. 681). Were the new hires discriminated against in any way, such as not receiving adequate training or pertinent information because of their race, age or gender? It is worth investigating whether the supervisor could have been discriminating against any of the new employees; contributing to or allowed any hostile or harsh working conditions; or violating any other labor laws. If so, then the supervisor should be terminated. It is equally important to consider whether the supervisor was a victim of discrimination or other hostile working conditions. Last, it is important to be aware of any potential violations of employment contracts, workers health and safety regulations, immigration laws, or labor unions. Regardless whether the new employees or supervisor are terminated, it is important to thoroughly investigate the circumstances and document the reasons for any termination.

WHETHER TO ALERT AUTHORITIES

As described throughout, a voluntary recall of the adulterated pet food products would best comply with pet food regulations, as well as tort and contract laws. A voluntary recall is when a company recalls a product on its own initiative, as opposed to a product recalled by the FDA. Typically, however, the FDA gives companies a chance to voluntarily recall products before it issues an FDA recall. Most recalls are voluntary.

However, simply because a recall is “voluntary” does not mean it is not legally mandated (Bloom, 2015). The Federal Food, Drug, and Cosmetic Act (FFDCA) requires that “all animal foods, like human foods, be safe to eat, produced under sanitary conditions, contain no harmful substances, and be truthfully labeled" (FDA, Pet Food). Precious Products has now violated these rules, in that the adulterated pet food is no longer safe and is not truthfully labeled.

Other FDA regulations (e.g. 21 CFR §507) reiterate these same requirements, but 21 CFR §507.25(a)(7) also states that "if animal food becomes adulterated, it must be rejected, disposed of, or ...processed to eliminate the adulteration." Presumably, this means the company needs to eliminate all the adulterated product, even if it was already distributed. Furthermore, as summarized above, 21 CFR §507.50(b)(1) requires a reanalysis of the company’s food safety plan if a problem is found, which would trigger corrective action/preventive controls, which would trigger a recall. Based on these regulations, it can be said that a company is legally required to issue a voluntary recall, once they become aware of the problem. Again, in terms of ethical behavior, the company should voluntarily recall the products on its own accord not just because of legal obligations, but because it *desires* to provide safe, high-quality products to consumers. The company and its agents should *desire* to resolve the problem before any harm or loss occurs, regardless of cost or loss of reputation.

WHETHER TO ALERT THE PRESS

Since a recall should be issued, and a recall involves notifying the public, then indeed the press should be notified. The company needs to notify the FDA, the consumers, and the general public that the Master Mix pet food products are unsafe and need to be returned to the company or otherwise disposed of.

While alerting the press fulfills procedural requirements in a recall, it also gives the company a chance to reassure customers in its own words that the recall is preventative, and that

there does not appear to be an immediate threat, since the product must be consumed for an extended period of time before causing kidney failure. Obviously, the company can only say this if it acts quickly and before any animals get sick or die. The company can also reassure its vendors and suppliers that the voluntary recall will minimize loss of market share, especially if action is taken quickly.

The best way to handle the press release is to first make sure you have a qualified team, either in-house or hired out. The FDA may also provide guidance on issuing the press release. Second, Precious Products should make sure it has a response team in place, to handle calls from customers or suppliers, complaints, and the like. In order to mitigate its public image, the team needs to be responsive, helpful, respectful, and caring towards all stakeholders. Third, the response team needs to put together a specific plan for customers to return the products, and make sure the plan gets carried out.

An important consideration is whether the president or other officers may want to remain silent throughout the process. It is not yet known whether anyone will suffer harm or loss and file suit. The president and other officers could potentially be held personally liable, and anything he says could be used against him in court. On the other hand, a statement from the president would carry more weight in public relations. It would show great leadership and that the company endeavors to follow ethical standards. The president should show that he did everything in his power to rectify the situation as soon as possible, and that the company is doing everything it can to prevent the problem from ever happening again. Of course, the president should only say this if its true.

WHAT TO DO ABOUT THE BOARD OF DIRECTORS

As illustrated above, Precious Products has already broken several laws with the addition of the protein supplement, and the company's next actions will determine whether additional laws are broken. Specifically, the company already broke laws relating to breach of nonconforming goods, breach of warranty, consumer laws, and various FDA regulations relating to safety, labeling, operations management, and quality control. If the company fails to recall the adulterated products, then it will have violated FDA regulations under 21 CFR §507.33. If the pet food continues to be consumed and pets start getting sick or dying, then harm and loss will have occurred, in which case Precious Products would be guilty of more serious offenses,

including fraudulent misrepresentation, negligence, strict liability, corporate criminal liability, and product liability. Such circumstances would be catastrophic to the company, especially in terms of multiple lawsuits, legal fees and fines, and an irrevocably tarnished public image. Furthermore, those directors and officers involved in the decision-making could be held personally liable for crimes committed. The company's next actions will be pivotal in the future of the company, its leaders, and all stakeholders.

Surprisingly, in the case of Precious Products, the board of directors has ordered the president to forget that anything happened. In other words, the board has directed the president not to alert authorities or the press, nor recall the adulterated products. As an officer of the company, the president is in a precarious situation. The president needs to decide whether to abide by the board's instructions.

It is unclear in this case whether the president of Precious Products is also the CEO or some other type of officer. If the President is also the CEO, he would report to the Board of Directors. If he is second in command, then he would report to the CEO, who would report to the Board of Directors. The Board reports to the owners or shareholders of the company. For simplicity sake, it is assumed that the President is also the CEO of Precious Product Corporation, and that he is not a director.

To decide the best course of action, the president should look at his duties and obligations as an officer; his duties as an agent of the company; his personal liabilities; and his own ethical and moral compass. The president then needs to determine and weigh his options.

Duties and liabilities of directors and officers. The duty of care and duty of loyalty are particularly important in this situation. "As fiduciaries, directors and officers owe ethical – and legal – duties to the corporation, and the shareholders as a whole. These fiduciary duties include the duty of care and the duty of loyalty." (Clarkson, pg. 778-779). Directors and officers who fail to exercise due care results in harm to the corporation or its shareholders can be held liable for negligence.

The duty of care for a corporate officer (and director) is defined as acting in "good faith, exercise the care that an ordinarily prudent person would exercise in similar circumstances, and to do what she or he believes is in the best interests of the corporation" (Clarkson, pg. 779). One exception to this is when the "business judgment rule" applies, which means the officer made an honest mistake of judgment. To qualify as under the business judgment rule, the officer must

have done his best to make an informed decision; had a rational basis or the decision; and show there was no conflict of interest between his duty to the company and his personal interests (Clarkson, pg. 779). Last, it is important to note that if a director disagrees with any decisions made in a board meeting, that director can (and should) enter a "dissent" into the board minutes. If the dissent is not entered, the assumption will be that the director agreed to the decision. This is important because if a decision later leads to negligence or some other corporate liability, those directors that dissented are rarely held personally liable (Clarkson, pg. 779).

The duty of loyalty is defined as a director's or officer's loyalty or faithfulness to the best interests of the corporation. In other words, "directors and officers [are required] to subordinate their personal interests to the welfare of the corporation" (Clarkson, pg. 780). They must not put their personal interests above the interests of the corporation. This conflict of interest can be manifested in issues of insider trading, favoring personal financial gain over minority shareholders, taking advantage of corporate opportunities, etc.

It is important to note that corporate directors and officers are personally liable for any crimes they intentionally or unintentionally commit. Additionally, they may be held liable for the actions of their employees. Under the *responsible corporate officer doctrine*, a court "may impose criminal liability on a corporate officer despite whether he or she participated in, directed, or even knew about a given criminal violation" (Clarkson, pg. 178.) He may answer to the board of directors, who answer to the shareholders, but he is also responsible for his own actions and potentially criminal behavior.

The president of Precious Products needs to consider his duty of care, duty of loyalty, and personal criminal liability when deciding whether to obey the board's command. As discussed throughout, it is in the company's best interest to recall the adulterated products; should the president initiate the recall, such action would satisfy his duty of care. Furthermore, it is not in his *personal* best interest to recall the products, since doing so would upset the board and jeopardize his career; therefore, his duty of loyalty would not be breached. Even in the unlikely event that the recall turns out to be a bad decision, he could apply the business judgment rule, in that he did his best making an informed decision with rational basis and no conflict of interest.

Fiduciary duty of agents and principals. The president, as an agent of the company, has a fiduciary duty to act *solely* in the best interest of the principal, which is the company and shareholders. This fiduciary relationship is based on trust and confidence. (Clarkson, pg. 624.)

An agent owes the principal five duties: performance (i.e. skillfully perform his duties); notification (i.e. inform the principal of all relevant information); loyalty (i.e. act solely for the benefit of the principal); obedience (i.e. "follow all lawful and clearly stated instructions of the principal"); and accounting (i.e. make available an account of all property and funds received and paid out). (Clarkson, pg. 631, 633). Of particular importance in the case of Precious Products is the president's duty of obedience: "the president must follow all ***lawful*** [emphasis added] and clearly stated instructions of the principal." In the pet food case, since multiple laws were broken in knowingly selling defective products, then the board's instructions to ignore the problem should also be considered unlawful. Therefore, in this situation, the president's duty of obedience can and should be broken, in a sense that he should *not* follow the *unlawful* instructions received by the principal/board. He needs to take corrective action, whether it be initiating a voluntary recall, being a whistle-blower (discussed below), or notifying the press. In doing so, he is still fulfilling the other four duties of performance, notification (even if the board didn't agree), loyalty (since he's ultimately acting for the benefit of the company), and accounting.

Furthermore, the principal could accepts responsibility for an unauthorized act of an agent. This is known as ratification. When this happens, "the principal is bound to the agent's act, and the act is treated as if it had been authorized by the principal from the outset" (Clarkson, pg. 644). In the case of Precious Products, should the president decide to recall the products without the board's authority, then the board would have the choice whether to ratify the act. If the board (foolishly) decides *not* to ratify the act, they risk further legal action against the company, as well as a tarnished public image.

PRESIDENT'S OPTIONS

1. Raise the issue at a Board of Directors meeting. We are not told in this case whether the issue was discussed at a board meeting. Assuming it was *not,* the president should consider presenting the issue at an emergency board meeting. Board meeting decisions are documented in the minutes, and some board members can "dissent" so that they're not held personally liable later for a bad decision. If the president brought the issue before the board at such meeting, presenting all the facts and risks at the meeting, this would force the directors to put their decision in writing. What director would agree to the risky (and illegal) decision to "forget about it"? Bringing the issue to a board meeting might compel the directors to take corrective action

and initiate the recall. This is the most favorable option. (Again, it is assumed that the president is not a director. If he were a director, he should most definitely "dissent" to the board's decision to ignore the problem.)

2. Initiate the recall without the board's approval. Should the board still decide to ignore the problem, the president might consider initiating the recall, even without the board's approval. As explained above, doing so would not violate the president's duty of care or loyalty, nor would it violate his fiduciary duty as agent. If the truly believes the company did something unethical or illegal, and if the president truly believes it's in the company's best interest to correct the problem, then corrective action would be in line with his duties as an officer and agent. Moreover, if the board decided to fire him for trying to protect consumers, how would that look in terms of public image? The board would have to be careful in how it responds to the media about the president's actions; the board would presumably want to show support for the recall, as that is in the best interest of the company.

3. Protection for Whistleblowers. If initiating the recall without the board's approval is problematic, the president should consider getting protection as a whistleblower. Under the Whistleblower Protection Act of 1989 and Whistleblower Protection Enhancement Act of 2012, the president has an option to report the activities of Precious Products to the Securities and Exchange Commission. If the SEC takes on the case, the president could obtain protection from any retaliation on the part of Precious Products, and the company would be forced to appropriately address the problems. As described by the SEC:

> "A federal agency violates the Whistleblower Protection Act if it takes or fails to take (or threatens to take or fail to take) a personnel action with respect to any employee or applicant because of any disclosure of information by the employee or applicant that he or she reasonably believes evidences a violation of a law, rule or regulation; gross mismanagement; gross waste of funds; an abuse of authority; or a substantial and specific danger to public health or safety" (SEC, 2019).

This course of action would protect the president against retaliation from Precious Products; fulfill his legal obligations to the company and to the public; and help get the dangerous products off the market.

4. Ignore the problem. The president has the option to comply with the board's instruction. In doing so, he is putting the company at greater legal risk, potentially costing the

company billions of dollars in fines, legal fees, and a tarnished reputation. The company has already broken various laws, which will be costly. But as animals (and potentially humans) get sick and/or die, then the company will have broken many more laws, especially tort laws of negligence, fraud, strict liability, product liability, and corporate criminal liability. This would be substantially more costly than the recall. Furthermore, ignoring the problem and allowing this to happen puts not only the company at legal risk, it also puts the president at risk personally. This course of action is not recommended, as it is illegal, unethical, and immoral.

5. Resign. As a last resort, the president might resign from the company. This is the least desirable and least helpful option, however. The president's resignation would not be in anybody's best interest, including his own. The problem of the dangerous products would not get resolved; the board would continue its unethical behavior; and the president would be out of a job, with limited options for his next employment. Furthermore, he still would likely be indicted several years down the road for contributing to all the animal deaths, and maybe a few human deaths.

CONCLUSION

Considering the multiple laws that have already been broken, the president needs to act on behalf of the company to avoid breaking more laws and violating ethical standards. As an officer of the company, he needs to satisfy his duties of care and loyalty, as well as his fiduciary duty, in doing so. He needs to act in the best interest of the company, which is to recall the adulterated products, in order to avoid harm and loss of a multitude of animals, and maybe even some humans. He needs to compel the board to initiate the voluntary recall. If the board refuses to do so, the president should initiate the recall himself, even against the wishes of the board. This course of action minimizes financial loss, legal liabilities, and a blow to the company's public image. Furthermore, doing so will most likely relieve the president of personal criminal liability that would likely take place if he ignores the problem.

REFERENCES

Bloom, Dave. (Nov. 9, 2015). “What ‘Voluntary’ Recall Means and Why You Should Care,” SnackSafely.com newsletter. Retrieved on April 21, 2019, from: <https://snacksafely.com/2015/11/what-voluntary-recall-means-and-why-you-should-care/>.

Clarkson, Kenneth, et al. (2012). *Business Law Text and Cases: Legal, Ethical, Global and Corporate Environment, 12th ed*. Mason, OH: Cengage Learning.

Code of Federal Regulations. (March 21, 2019). Title 21, Chapter I, Subchapter E, parts 504, 507. Retrieved on March 25, 2019 from: <https://www.ecfr.gov/cgi-bin/text-idx?gp=&SID=fe2dee7e53a5bb6de6d23fc93a127626&mc=true&tpl=/ecfrbrowse/Title21/21CIsubchapE.tpl>.

Dictionary.com. (2019). “What’s the Difference Between Morals and Ethics?” Retrieved on March 24, 2019, from: <https://www.dictionary.com/e/moral-vs-ethical/>.

U.S. Department of Justice Office of Public Affairs. (March 19, 2014). *Justice Department Announces Criminal Charge Against Toyota Motor Corporation and Deferred Prosecution Agreement with $1.2 Billion Financial Penalty* [Press release]. Retrieved on April 9, 2019, from: <https://www.justice.gov/opa/pr/justice-department-announces-criminal-charge-against-toyota-motor-corporation-and-deferred>.

U.S. Food and Drug Administration. (Date unknown). *FDA’s Regulation of Pet Food*. U.S. Department of Health and Human Services. Retrieved on March 24, 2019, from: <https://www.fda.gov/AnimalVeterinary/ResourcesforYou/ucm047111.htm>.

U.S. Food and Drug Administration. (Date unknown). *Pet Food Labels - General*. U.S. Department of Health and Human Services. Retrieved on March 24, 2019, from: <https://www.fda.gov/animalveterinary/resourcesforyou/ucm047113.htm>.

U.S. Food and Drug Administration. (Date unknown). *Pet Food*. Department of Health and Human Services. Retrieved on April 22, 2019, from: <https://www.fda.gov/animalveterinary/products/animalfoodfeeds/petfood/default.htm>.

U.S. Food and Drug Administration. (April 22, 1996). “Inapplicability of the Dietary Supplement Health and Education Act (DSHEA) to Animal Products.” *Federal Register*, Vol. 61, No. 78. Retrieved on March 24, 2019, from: <https://www.govinfo.gov/content/pkg/FR-1996-04-22/pdf/96-9780.pdf>.

U.S. Food and Drug Administration. (Oct. 2017). “Current Good Manufacturing Practice Requirements for Food for Animals.” *Guidance for Animals*, U.S. Department of Health and Human Services. Retrieved on March 24, 2019, from: <https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM499200.pdf>.

U.S. Securities and Exchange Commission. (Date unknown). “Information on Whistleblower Protection Act [of 1989] and Whistleblower Protection Enhancement Act [of 2012].” Retrieved on April 15, 2019, from: <https://www.sec.gov/eeoinfo/whistleblowers.htm>.