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Synthetic Hormone Use In Beef And The Us Regulatory Dilemma

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SYNTHETIC HORMONE USE IN BEEF AND THE US REGULATORY DILEMMA

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INTRODUCTION

Since the 1900s farmers and food producers have looked for ways to increase profits in their respective industries. Beginning in the early 1900's one way for food producers to accomplish increased profit margins was through the use of synthetic hormones on their cattle. Once animals were given synthetic hormones, they grew bigger, in shorter periods of time, while eating less feed than they normally required. This practice exploded in the early part of the century, effectively increasing profits and production throughout the industry.

However, this increase in production did not come without risks. When a hormone is used in a food-producing animal, such as a cow, some residues of that hormone may appear in the slaughtered meat from the animal used for human consumption. The regulation of hormones used in beef marketed and sold for human use involves both food safety regulations as well as drug regulation. As a result, two government agencies, the U.S. Food and Drug Administration ("FDA") and United States Department of Agriculture ("USDA"), were responsible for ensuring the public safety of these products. This was a very complex way to approach the problem, so the two agencies signed a "memorandum of understanding" setting out procedures and guidelines for both to follow in an effort to avoid overlap.¹

Some synthetic hormones used in food production, such as diethylstilbestrol ("DES"), have been proven to be carcinogens, or cancer causing substances. While the FDA and USDA have passed regulations to ensure human exposure to these residual carcinogens are minimal, the regulations are in a state of flux, being both under inclusive and over inclusive, and at times wholly ineffective. The regulations can include too many hormones, including those that are safe

¹ U.S. Food and Drug Administration and U.S. Department of Agriculture, *Memorandum of Understanding concerning Information Sharing Related to Food Safety, Public Health, and Other Food-Associated Activities*, MOU 225-11-0019 [hereinafter *Memorandum of Understanding*].

and beneficial for the food industry, and at other times too few substances, allowing potentially carcinogenic hormones to enter the food supply. This came to fruition with DES, as poor enforcement, poor detection methods, and unclear regulations led to potentially hazardous meat finding its way on to grocery store shelves.

In addition to the potential increase in the risk of getting cancer, synthetic hormones have also been linked to various other conditions. Several occurrences of the early onset of puberty, males growing breasts, and reproductive problems have all been traced back to synthetic hormones in beef.² These risks proved to be too great in many countries around the world such as Italy, Denmark, and Germany, who have completely banned the use of hormones in meat production starting in the early 1960s.³ This led to a Europe wide ban in 1977 after young men started developing breasts, causing many to blame synthetic hormones.⁴

In the United States, it is the responsibility of the USDA to inspect the beef, both before and after slaughter. This is done through the Food Safety Inspection Service (“FSIS”). However, for many years there was a relaxed attitude toward the inspection of meat products, and scientific testing lagged in the ability to determine safe levels of residual hormones for human consumption. These deficiencies came into the public’s purview during the hey-day of DES.

This paper will examine the United States Governmental regulation overseen by the FDA and USDA with regards to the use of additives in the beef industry. Part I will explore early attempts at regulation and the procedures for detection. Part II will address the public’s concern about meat treated with synthetic hormones as well as current regulations, specifically focusing

² Michael Wayne, *The Meat You Eat: Steroid Use in Livestock, Low Density Lifestyle, Low Density Lifestyle*, <http://www.lowdensitylifestyle.com/the-meat-you-eat-steroid-use-in-livestock/> (last visited Dec. 1, 2013).

³ Annamaria Passantino, *Steroid Hormones in Food Producing Animals: Regulatory Situation in Europe*, Intech Open 1 (Feb. 22, 2012), <http://cdn.intechweb.org/pdfs/28666.pdf>

⁴ *Id.*

on the FDA and the enactment of the “Delaney Clause”, in response to DES, and its effect on the industry. In conclusion, this paper will propose some potential ways in which the FDA and USDA can better use its authority to properly regulate potentially carcinogenic substances such as synthetic hormones.

I. History of Hormone Use

A) What are Hormones?

Hormones are chemicals produced in specific glands inside an organism and then transported by the bloodstream to other parts of the body.⁵ The hormone travels through the blood stream until it finds a specific cell with receptors that match its chemical compound, to which the hormone attaches delivering its message.⁶ In both humans and animals, hormones influence various bodily functions, including metabolism, digestion, growth, and reproduction.⁷ The most important functions of hormones for use in beef production are those controlling growth and metabolism. Synthetic hormones allow farmers to have cattle with higher growth rates, along with decreasing metabolism rates to lower the amount of cattle feed consumption, which leads to greater efficiency in the industry.

A hormone that is produced naturally by humans and animals is called an “endogenous” or “natural” hormone.⁸ Hormones chemically created to mirror natural hormones are called “synthetic” hormones.⁹ Synthetic hormones were originally extracted and synthesized from

⁵ See generally Claire Gibson, *Hormones and Behavior: a Psychological Approach*, Project Muse, <http://muse.jhu.edu/journals/pbm/summary/v053/53.1.gibson.html> (last visited Dec. 2 2013).

⁶ *Id.*

⁷ Passantino, *supra* note 3.

⁸ *Id.*

⁹ Renu Ghandi & Suzanne M. Snedeker, *Consumer Concerns About Hormones in Food*, Fact Sheet #37 (June 2000).

animal urine, an incredibly difficult process.¹⁰ All the glands that create hormones are part of a network in the human body called the “endocrine system.”¹¹

While hormones are necessary for vital human and animal development, hormones can also be toxic to living organisms when certain criteria are met in the endocrine system.¹² The toxicity of hormones has been attributed to several theories. Among them are the belief that receiving an excessively large dose of the hormone and receiving the hormone at an inappropriate development stage, or in the wrong sex, can cause harmful effects to the body.¹³

When occurring naturally in the body, the rate of hormone production and secretion is regulated by the homeostatic negative feedback system.¹⁴ When certain glands have produced too much of a particular hormone, negative feedback is triggered in the brain and the production is halted.¹⁵ Without being regulated, a disability can then result from the under or over production of hormones in the body.¹⁶

By logical extension, it would seem the body knows best when it comes to excessive hormones being present in the body since it has an innate ability to shut down production and avert the risk of toxicity. Thus farmers using high concentrated doses of the hormones without the bodies consent would naturally cause concern among many scientists and industry professionals as to the safety of synthetic hormone residues in food.

B) Hormone Use in Animals

¹⁰ KMFDallas, *DES Timeline from Discovery to 2013*, CNN iReport <http://ireport.cnn.com/docs/DOC-735079> (last visited Nov. 22, 2013).

¹¹ Frank S. Bloch, *Block on Social Security* § 3:21 (May 2011).

¹² See Revised Medical Criteria for Evaluating Endocrine Disorders, 74 FR 66069-01 (2009).

¹³ *Id.*

¹⁴ PETER HUTT, RICHARD MERRILL & LEWIS GROSSMAN, *FOOD AND DRUG LAW*, 1112, (Foundation Press, 3rd ed., 2007).

¹⁵ See generally *Hormones*, Medline Plus, (Nov. 14, 2003)

<http://www.nlm.nih.gov/medlineplus/hormones.html> (last visited Dec. 20, 2013).

¹⁶ *Id.*

Certain hormones give farmers the ability to make young animals gain weight more quickly, while also using less feed. The introduction of hormones into animals began to increase in the early 1930's, when it was discovered that cows injected with bovine growth hormone ("BGH") produced more milk.¹⁷ Around the same time, the female sex hormone estrogen was shown to increase cattle size.¹⁸

Hormones such as estrogen are administered to cattle by an ear implant, or "pellet", placed beneath the skin of the animal's ear.¹⁹ The pellet is designed to release a specific dose of the hormone over an extended period of time.²⁰ When an animal is slaughtered, the industry practice is to remove the ears and discard them, ensuring they will never be available for human consumption.²¹

C) Human Concern

Studies suggest nearly 50% of individuals in the U.S. are unaware they have been exposed to synthetic hormones in beef.²² However, consumers are concerned about being exposed to the synthetic hormones given to animals, and whether the residues left in the meat can be harmful to their health. Coupled with the fact that humans perceive risks of "unknown" technology greater than "known" technology, synthetic hormones create an enormous tension for regulators.²³ People feel that traditional food is safer since we have been consuming it for

¹⁷ See generally Brian Randall, *The Controversy Over Added Hormones in Meat and Dairy*, NYU Langone Medical Center, <http://www.med.nyu.edu/content?ChunkIID=90869> (last visited Nov. 26, 2013).

¹⁸ KMFDallas, *DES Timeline from Discovery to 2013*, CNN iReport <http://ireport.cnn.com/docs/DOC-735079> (last visited Nov. 22, 2013).

¹⁹ *Id.*

²⁰ *Id.*

²¹ *Id.*

²² Randall, *supra* note 17.

²³ Paul Slovic, *Perception of Risk*, 236 SCI 280, 283 (1987).

hundreds of years.²⁴ The current regulatory bodies make the public acutely aware of the risks of artificial enhancements in food, such as synthetic hormones, without acknowledging the dangers of “natural” foods they consider safe.²⁵

Having been proven to have potentially harmful effects on humans it is easy to see how public concern would escalate in response to any reported cases of ill effects due to beef consumption. However, the public has difficulty understanding the actual risk associated with the hormones. The public wants to know, with regard to treated animals, if there are excessive hormones left in the meat they produce, and if so, how is it safe to eat?

Studies show that a lifetime exposure to natural hormones, which many consider safer than synthetic, increases the risk of cancer²⁶. Dr Samuel S Epstein, Chairman of the Cancer Prevention Coalition has said, “Not surprisingly, but contrary to longstanding claims by the U.S. Food and Drug Administration and the U.S. Department of Agriculture, residues of these hormones in meat are up 20-fold higher than normal in recent years.”²⁷ Dr. Epstein has conducted studies showing that childhood cancer has increased by 38% since 1975, in large part he believes to hormone residues present in beef.²⁸ It is only natural that the public would want synthetic hormones to be looked at with increased scrutiny by regulatory agencies.

Unfortunately, testing procedures for the detection of hormone residuals are inadequate. It was not until 2010 that the Government revamped the National Residue Program (“NRP”),

²⁴ D. Feinberg, *A Cookbook for a Consistent Food Safety Standard for Carcinogenic Foods: Looking to the Ingredients of a Food Rather Than Its Recipe*, 5 J. PHARMACY & L. 67, 76 (1995).

²⁵ 21 U.S.C § 342(a).

²⁶ See BCERF Fact Sheet #09, *Estrogen and Breast Cancer Risk: What is the Relationship?*

²⁷ *Hormones in U.S. Beef Linked to Increased Cancer Risk*, Prevent Cancer

http://preventcancer.com/consumers/general/hormones_meat.htm (last visited Nov. 30, 2013).

²⁸ *Id.*

who conducts the testing on all animal products.²⁹ The NRP collects data on animals and reports the findings on the FSIS website.³⁰ In 2010, the procedures allow them to tests for 55 pesticides, 9 antibiotics, and 50 other chemicals. In years past, they could only test for one of these substances at a time.³¹ Although the tests can now detect more substances, experts are still not sure what level of hormone residue is safe for human consumption.

Further, even if we knew the safe amount of hormones humans could consume, science detection capabilities are still unable to detect minute traces of hormones in beef, and therefore may not be capable of detecting potentially harmful levels of carcinogens.

II. The Rise and Use of DES

A) Early Response and Regulation of DES

Diethylstilbestrol is a hormone that was first synthesized from a coal-tar derivative by English biochemist Charles Dodds in 1938.³² Dodds advocated DES solely for use in in women who had menopausal symptoms.³³ At the time, many researchers felt DES had the potential to be carcinogenic, since natural estrogens were known to cause cancer, and DES (a synthetic estrogen) had more potent estrogenic effects than natural hormones.³⁴ The FDA shared this apprehension when first dealing with DES; initially rejecting the approval of DES for use in menopausal women under the principle that in the absence of scientific research showing

²⁹ Helena Bottemiller, *USDA to Ramp Up Drug Residue Testing for Meat and Poultry*, Food Safety News (July 2, 2012) <http://www.foodsafetynews.com/2012/07/usda-to-ramp-up-drug-residue-testing-for-meat-and-poultry/#.UqXr-o7R3zI> (last visited Dec. 20, 2013).

³⁰ *Id.*

³¹ *Id.*

³² Randall, *supra* note 17.

³³ *Id.*

³⁴ See generally Chemista, *The Silent War: An Exploration into Understanding the Complexities of the Chemical Age, Synthetic Revolution, and the toxins that impact us all*, *The Silent War* <http://renchemista.wordpress.com/2010/06/05/diethylstilbestrol-des-information-timeline/> (last visited Nov. 28, 2013).

harmful effects the drug was not necessarily inherently “safe” for use in humans.³⁵ However, this conservative approach to regulating DES did not last.

Due to political pressure, the FDA reversed its decision in 1941, approving the use of DES in menopausal women.³⁶ This flip meant the FDA was no longer following a “conservative approach,” but instead was putting the burden on opponents of DES to show the hormone caused harm.

At the same time, the FDA rejected DES use in animals. A request made by a farmer in 1944 to use DES on roosters was refused because safety studies had not been completed on possible residues left over in meat, asserting the burden lies on the DES producers, not on consumers.³⁷ Instead, the FDA required the “New Drug Application” procedures be followed, where a company submits a request with several scientific tests proving a drug’s safety.³⁸ The DES producers never complied, as they refused to provide the scientific evidence required for approval.³⁹

The FDA continually rejected NDAs for DES use in poultry throughout 1946 but the FDA abruptly reversed its position in 1947, although no new information or studies had been discovered.⁴⁰ It is believed that a Houston doctor, Karl John Karnaky, and his research played a significant role in the reversal. Doctor Karnaky treated pregnant women with large amounts of

³⁵ *Id.*

³⁶ Randall, *supra* note 18.

³⁷ C.W. Crawford, *Assistant Commissioner of Food and Drugs, FDA, to Mr. James A. Austin, Jensen-Salsbery Laboratories, Inc.*, Kansas City, MO. 5/8/44. A1, Entry 5, General Subject Files, 38-74. (1944).

³⁸ 21 U.S.C.A § 301 (1938).

³⁹ See generally Nancy Lanston, *Modern Meat: Hormones, Livestock, and Consumers in the Post-WWII Era* <http://www.yale.edu/agrarianstudies/colloqpapers/05langston.pdf>

⁴⁰ See generally Douglas & London, *DES Timeline*, Douglas & London Lawfirm <http://www.douglasandlondon.com/docs/DES-Timeline.pdf>

DES and no ill effects resulted.⁴¹ By its own logic, the FDA then determined that if large doses were okay in humans, then small doses must be safe as well.⁴²

With this mindset, the FDA went on to approve the use of DES in cattle feed, immediately raising concerns among many scientists and consumers. The public wondered how the FDA could explicitly state DES is harmful in poultry, then turn around and approve DES use in cattle. The answer came from studies performed at several separate universities and journals citing indications that oral DES administered at high levels might be useful to cattle even though it did not help with chickens.⁴³

In 1953, Wise Burroughs published a report showing “cattle gains could be increased substantially and feed costs could be reduced by placing 5 mg or more of DES in the daily supplemental feed to each steer.”⁴⁴ Burroughs went on to conclude that DES led to a 35% growth increase in cattle, while slashing feed cost by nearly 20%.⁴⁵

After the Wise Burroughs findings, the FDA approved DES on November 1, 1954, with one key requirement: any cattle treated with DES was to have it removed from its feed 48 days prior to slaughter.⁴⁶ This went into effect even though the tests created to measure the hormone residues in poultry tissues were not yet sophisticated enough to detect residues in beef.⁴⁷ With these restrictions, DES went on to be used in nearly 80% of all United States cattle.⁴⁸ During the

⁴¹ Lanston, *supra* note 39.

⁴² *Id.*

⁴³ *Id.*

⁴⁴ A.P. Raun and R.L. Preson, *History of Diethylstilbestrol Use*, Burroughs et al, THE EFFECTS OF TRACE AMOUNTS OF DIETHYLSTILBESTROL 66, 67.

⁴⁵ *Id.*

⁴⁶ *See Hess & Clark, Div. of Rhodia, Inc. v. FDA*, 495 F.2d 975, 979 (D.C. Cir. 1974).

⁴⁷ Raun and Preson, *supra* note 44.

⁴⁸ *Id.*

drug's prime between 1954 and 1972, consumption of beef nearly doubled, leading to increased scrutiny and consumer concern over what it was exactly they were putting into their bodies.

Along with this approval, DES quickly became a common tool for farmers looking to fatten their cattle using less food. Shortly after being approved for use in beef, DES was estimated to having been used in nearly 90% of the cattle feed in America.⁴⁹

During an FDA Symposium of Medicated Feeds in 1956, research was presented showing small doses of DES could induce cancer more readily than large doses.⁵⁰ These studies completely dispelled Doctor Karnaky's research, which the FDA explicitly relied on when approving DES in the first place.

What occurred was a severe conflict of interest in the regulatory agencies. Whose interests were they to represent? Was it that of the farmers and food producers, or the safety and health of the public? This existential dilemma made it very difficult to find a solution beneficial to everyone, although the government did make an effort to do so.

B) The Introduction of the Delaney Clause

In the 1950's, the public grew increasingly apprehensive about chemicals being added to their food. Congressman James Delaney was appointed to lead an investigation into the matter, and revise the bill.⁵¹ Congressman Delaney found that the USDA felt the industry was being victimized, claiming it was possible for research to go on indefinitely without discovering all possible negative consequences of hormone use.⁵² The FDA however advocated for changes in

⁴⁹ *Id.*

⁵⁰ Lanston, *supra* note 39.

⁵¹ H.R. 7798, 85th Cong., 1st Sess. (1957).

⁵² H.R. 13,254, 85th Cong., 2d Sess. (1958).

the law, asking that rules be put in place for companies to prove a hormones safety before it was used.⁵³

The concerns of consumers and the farms profitability interests had peeked, and it was up to Congressman Delaney and his House Sub Committee to determine the proper solution.⁵⁴ The Delaney Hearings led to an amendment of the Federal Food, Drug, and Cosmetics Act (“FDCA”), requiring food producers to show the animal feeds they used were safe for the animal and any animal parts consumed by humans would not have residues above a pre-determined safe level.⁵⁵

However, one important caveat was what was dubbed the “Delaney Clause”, which explicitly stated:

the Secretary of the Food Drug Administration, shall not approve for use in food any chemical additive found to induce cancer in man, or, after tests, found to induce cancer in animals.⁵⁶

Instead of the prior assumption by the FDA that said if the science cannot detect it, it must not exist, this showed they realized the science at the time could not measure harmful residues, but that did not mean there was not a possibility they actually were harmful. This had a downside however, as it treated some hazardous chemicals with a de minimus attitude, giving the administration discretion to deal with what they considered acceptable levels,⁵⁷ and conversely said any carcinogenic substances as hazardous per se.⁵⁸

⁵³ Fred Degnan & Gary Flamm, *Living with and Reforming the Delnaey Clause*, 50 FOOD & DRUG L.J. 235, 236 (1995).

⁵⁴ Food Additives, Hearings Before a Subcomm. Of the House Comm. On Interstate and Foreign Commerce, 85th Cong., 1st and 2d Sess. 171 (1958).

⁵⁵ *Id.*

⁵⁶ Federal Food, Drug, and Cosmetic Act, §§ 706, 706(b)(5)(B), as amended, 21 U.S.C.A. §§ 376, 376(b)(5)(B) (1982).

⁵⁷ *Monsanto Co. v. Kennedy*, 613 F.2d 947 (D.C. Cir. 1979).

⁵⁸ 47 Fed. Reg. 14464 (1982).

Naturally, the clause was met with an onslaught of opposition from the farming industry. A complete ban on any known carcinogen was incredibly unpractical because, as scientists point out, taking something as simple as sugar, and giving it to mice in high concentrated doses could cause cancer.⁵⁹ Did the Delaney Clause thus mean any food with sugar must be taken off grocery market shelves?⁶⁰ The Delaney Clause makes it possible that depending on certain assumptions, the same scientific data could be considered as having reached different outcomes.⁶¹

C) DES Provisio

The investigation led to a modification of the Clause in 1962, which was dubbed the “DES Provisio.” The DES Provisio permitted the use of DES in meat, so long as there would be no detectable residues in the finished product.⁶² Richard Merrill, in a long time study of DES, described the proviso as “contrasted with the Delaney Clause itself, the DES proviso makes the detection of residues in edible animal tissues, rather than the addition of the compound to animals or their feed, the critical inquiry.”⁶³ This satisfied the industry concerns, however it left lots of theoretical assumptions to be adhered to in order to work.

The FDA and USDA were responsible to do several things in order for the DES proviso to work. One task was to find a test for residues adequate to determine toxic levels.⁶⁴ Another was to diligently supervise and test enough meat that accurately represents the population of

⁵⁹ Leticia M. Diaz, *Sucralose: The Sugar of the New Millenium – FDA’s Role: A Hinderance or a Help*, 34 N.E. L. REV. 363, 372 (2000).

⁶⁰ *Id.*

⁶¹ Al Meyerhoff, *The Delaney Clause: Point/Counterpoint*, 19 EPA J. 42 (1993).

⁶² *Id.*

⁶³ Richard Merrill, *Regulating Carcinogens in Food: A Legislator’s Guide to the Food Safety Provisions of the Federal Food, Drug, and Cosmetic Act*, 77 MICH. L. REV. 171, 233 (1978).

⁶⁴ U.S. Department of Justice, *THE FOOD AND DRUG ADMINISTRATION’S DISCRETION TO APPROVE METHODS OF DETECTION AND TO DEFINE THE TERM “NO RESIDUE” PURSUANT TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT*, 19 U.S. Op. Off. Legal Counsel 247 (O.L.C.), 1995 WL 1767991 (1995).

meat used in today's market.⁶⁵ A third was to ensure farmers were administering the same doses among all animals, including those provided for testing.⁶⁶

It is not hard to see why the DES provision was inherently problematic. The farmer's conflict of interest was enormous, and relying on their "good faith" did not carry much weight when pitted against the added profits they would see from illegal DES use. However, the FDA did not have much of a choice aside from relying on the good faith of farmers, as government funding was cut, and the enforcement and feasibility of nationwide supervision and testing became increasingly dire.

A test was developed for the USDA in which DES could be detected at the 10 parts per billion ("ppb") level.⁶⁷ Test results in mice had shown tumors resulting from only a 6.5 ppb exposure to DES.⁶⁸ On its face, the testing employed by the USDA was not even capable of detecting below a safe level of consumption.⁶⁹ The regulators however approved the testing process, and began testing meats in 1965.⁷⁰ Violations of the Clause were found every single year.⁷¹

When testing first began, the FSIS, a branch of the USDA, would sample 600 cattle per year.⁷² To put it in perspective, there are over ten million cattle due to be slaughtered in 1965 alone.⁷³ The test results found DES above 10 ppb in .7% in 1965, 1.1% in 1966, and 2.6% in

⁶⁵ *Id.*

⁶⁶ *Id.*

⁶⁷ See generally Wade, *A Case Study of Regulatory Abdication Article*, <http://www.sciencemag.org/content/177/4046/335.extract.jpg> (last visited Nov. 29, 2013).

⁶⁸ *Id.*

⁶⁹ *Id.*

⁷⁰ *Id.*

⁷¹ *Id.*

⁷² Katheryn Klimko, *FDA's Contradictory Decisions Related to the Delaney Clause*, <http://dash.harvard.edu/handle/1/8963872> at 19, 21 (May 2011).

⁷³ *Id.*

1970.⁷⁴ From these results, it was clear that the DES proviso was not working, and there was no guessing how much of the meat being consumed was contaminated with the hormone.

Many felt this was a clear indication that change was warranted and, more importantly, needed to the DES proviso. Then, in 1970, the USDA cut its testing program by nearly 50%.⁷⁵ By a later dated FDA memo, it was estimated that most cattle going to market would be given nearly twice the DES they had received the years prior.⁷⁶

The Delaney Clause has since been gutted and no longer has any teeth when it comes to the enforcement of carcinogenic substances. When the Clause was enacted in 1958, there were only four known cancer causing substances that posed a threat to humans: soot, radiation, tobacco, and beta-naphthylamine.⁷⁷ As technology improved, testing abilities for carcinogenic substances likewise improved. The sensitivity testing capabilities of carcinogens could be detected nearly one million times greater than 10 ppb by the 1980's.⁷⁸

When Congress enacted the Clause, they did not foresee the current scientific ability of technology to detect incredibly small chances of carcinogenicity in commonly consumed foods. The Clause fails to provide specific guidelines for just “how much” carcinogenic a substance must be.⁷⁹ The FDA had to modify the clause to cope with these new advancements in detection technology. The FDA declared that for a substance to be deemed safe, it must result in a risk to humans of more than one in one million of developing cancer over one's lifetime.⁸⁰

⁷⁴ *Id.*

⁷⁵ *Id.*

⁷⁶ *Id.*

⁷⁷ *See generally* 51 Fed. Reg. 28331, 28343 (1986).

⁷⁸ *Id.*

⁷⁹ Klimko, *supra* note 72.

⁸⁰ D. Feinberg, *A Cookbook for a Consistent Food Safety Standard for Carcinogenic Foods: Looking to the Ingredients of a Food Rather Than Its Recipe*, 5 J. PHARMACY & L. 67, 76 (1995).

By the 1970's, the ability to detect substances added to beef increased dramatically, and the FDA adapted by adopting a "quantitative risk assessment" of measurement, which is both under inclusive and over inclusive.⁸¹ In one facet, it was able to reduce overregulation of chemical additives such as hormones because those that had incredibly low risks were allowed to be use in food products.⁸² However, the method involved "the mathematical extrapolation from high-dose laboratory animal data to derive estimates of the cancer risk associated with much lower human exposures from consumer products."⁸³ This method makes several assumptions, namely, assuming that laboratory mice are proper indicators of potential risk to humans.⁸⁴

The FDCA further complicated the Clause with a "generally recognized as safe" ("GRAS") exception. The GRAS exception allowed food additives that were generally accepted by experts as "safe" prior to 1958 to by pass any strict regulations set forth earlier in the Delaney Clause. The Act defines a "food additive" in relevant part:

Any substances the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affect the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, treating use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown to be safe under the conditions of its intended use; EXCEPT that such term does not include.. (4) any substance in accordance with a sanction or approval granted prior to the enactment of this paragraph 4 pursuant to this Act.⁸⁵

Thus, anything used in food prior to 1958, such as DES, was given less strict standards for compliance. This led some to question the Delaney clause as unfairly penalizing newly created substances and hormones over old.⁸⁶

⁸¹ See Merrill, *supra* note 14, at 12-16.

⁸² Klimko, *supra* note 72.

⁸³ FOOD AND DRUG LAW, *supra* note 14, at 1138.

⁸⁴ *Id.*

⁸⁵ 21 U.S.C. § 321(s) (2009).

⁸⁶ See, e.g., *A Cookbook for Consistent Food Safety Standard*, *supra* note 80, at 78.

III. The US Regulation Dilemma

A) The USDA

The United States Department of Agriculture (“USDA”), is a federal regulatory agency that governs farming and agriculture in the US.⁸⁷ In short, the USDA ensures public consumers that the meat they eat is safe from the time a cow is born, to the day it is placed on a backyard grill.⁸⁸ It is also the USDA’s responsibility to keep the public informed on numerous topics, including but not limited to: nutritional guidelines, biotechnology, and the risks/effects of disease.⁸⁹ The USDA is solely responsible for the oversight of any animal not treated with any drugs from the time it is born to slaughter.

The USDA continues to claim scientific evidence on synthetic hormones is inconclusive, and that the microscopic amount of hormones present in consumed meat may or may not cause health problems, including those listed above.⁹⁰ The USDA currently regulates hormones in food by setting a the Maximum Residue Level of hormone in beef, otherwise known as “MRL.”⁹¹ Animal organs are given different tolerance levels of MRL.⁹² A cow’s liver for example, is allowed higher MRL’s than their more commonly consumed meat, such as the shoulder.⁹³ In

⁸⁷ See generally United States Department of Agriculture, *Laws and Regulations* http://usda.gov/wps/portal/usda/usdahome?navid=LAWS_REGS&navtype=SU (last visited Nov. 28, 2013).

⁸⁸ *Id.*

⁸⁹ *Id.*

⁹⁰ THOMAS DUNLAP, DDT: SCIENTISTS, CITIZENS, AND PUBLIC POLICY. PRINCETON: PRINCETON UNIVERSITY PRESS, 67 – 69 (1981).

⁹¹ Ronald Schmidt & Gary Rodrick, *Food Safety Handbook* (2003)

<http://muhammadsabchi.files.wordpress.com/2010/04/food-safety-handbook.pdf>

⁹² *Id.*

⁹³ *Id.* at 406.

addition, the FDA has also historically prohibited hormones from being given to animals, which are close (within 48 hours) to being slaughtered.⁹⁴

One USDA branch is the Food Safety Inspection Service (“FSIS”). The Federal Meat Inspection Act (“FMIA”) provides the FSIS the authority to regulated meat-manufacturing plants, and oversees the safety and accurate labeling of meat, as well as humane conditions for animals.⁹⁵ With two agencies given the same responsibilities, it is hard to regulate without the fear of possibly making a contradictory decision to the other regulatory agency. This was supposed to be solved with a memorandum of understanding.

B) The FDA

The Federal Drug Administration (“FDA”) is a government entity that regulates food, drugs, vaccines, and animal products.⁹⁶ The FDA is an intricate part to the regulation of hormone along with the USDA since the “synthetic drug” is added to the animal while being raised and before slaughter.⁹⁷ The FDA regulates animal drugs, and therefore has oversight of beef that is treated with any type of drug in between birth and slaughter.

The FDA ensures that all animal drugs are safe for both the animals themselves, and the food they eventually produce for human consumption⁹⁸. There are three kinds of synthetic hormones currently approved by the FDA for use in cattle.⁹⁹ The approved synthetic hormones

⁹⁴ *Id.* at 406.

⁹⁵ Federal Meat Inspection Act, § 1 et seq., 21 U.S.C.A. § 601 et seq; *National Meat Ass'n v. Harris*, 132 S. Ct. 965 (2012).

⁹⁶ U.S. Department of Health and Human Services, *Protecting and Promoting Your Health* <http://www.fda.gov/default.htm> (last visited Nov. 28, 2013).

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ U.S. Food and Drug Administration, *Steroid Hormone Implants Used for Growth in Food-Producing Animals*, Product Safety Information <http://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/ucm055436.htm> (last visited Feb. 8, 2011).

are: trenbolone acetate, melengesterol acetate and zeranol.¹⁰⁰ While current federal regulations allow these hormones to be use in beef and sheep, it has been banned for use in poultry and pigs (hormones have not been shown to increase weight in pigs).¹⁰¹ The FDA has banned all use of synthetic hormones in poultry, due to scientific testing capabilities of detecting potential harmful effects easier in chicken products.

The FDA, however, has changed its approach to hormone withdrawal before animal slaughter. Initially, the FDA required that all synthetic hormones must be pulled from an animal's feed at least 48 hours prior to slaughter to ensure there are no residues in the finished product. The FDA's current stance, however, is that meat is safe for consumption at any time after the hormones are injected.

Congress passed The Federal Food, Drugs, and Cosmetics Act ("FFDCA"), in 1938, which gave the FDA the authority to oversee the safety and accurate labeling of food and drugs.¹⁰² Section 409 of the FDCA requires the FDA to evaluate beef through regulations and ensure safe use of additives in all foods.¹⁰³ The Federal Meat Inspection Act ("FMIA") provide the FSIS the ability to determine the safety of and regulations for meat and beef products in federally inspected facilities.¹⁰⁴

The Act requires that all "additives" to food be demonstrated as "reasonably certain" no harm could result from the additive.¹⁰⁵ A drug is only approved for use after the producer submits a "New Drug Application" for review to the FDA.¹⁰⁶ The drug producer will submit

¹⁰⁰ *Id.*

¹⁰¹ *Id.*

¹⁰² 21 U.S.C.A. § 301 (1982).

¹⁰³ 21 U.S.C.A. § 348 (1982).

¹⁰⁴ 21 U.S.C.A. § 601(m)(2) (1982).

¹⁰⁵ 21 U.S.C.A. § 341 – 350 (1982).

¹⁰⁶ 21 U.S.C.A. § 355 (1982).

clinical trials and test results, along with information on how the drug is produced, and any self-regulations over its production.¹⁰⁷ The FDA then determines whether the drug is safe and effective for its proposed use, whether the benefits of the drug outweigh the harm, and whether the methods of production are adequate to ensure safety and purity of the drug.¹⁰⁸ Once the FDA rules an additive safe, it then creates guidelines for the proper use to remain safe.¹⁰⁹

C) The Memorandum of Understanding

In the past, the FDA and FSIS have attempted to cooperate when handling issues with new ingredients on an as needed, case-by-case basis. However, since each agency must follow different statutory mandates, regulations sometimes have terms that are inconsistent and incompatible when taken together. This lack of consistency causes great inconvenience to people attempting to comply with both agencies' regulations when using hormones in beef products.

With both regulatory agencies are involved in overseeing the meat industry, it can be extremely difficult to be efficient without set procedures for each agency describing what their respective responsibilities are. Together, the USDA and FDA decided to simplify their respective responsibilities. This was accomplished with a "memorandum of understanding" ("MOA"), which was enacted between the FSIS and the FDA.

The FDA announced the MOA to make the process move much more seamless and for reviewing new drugs petitions. Instead of individual reviews, at different times, by the FSIS and FDA, drug producers need only file one application with the FDA for a government-wide

¹⁰⁷ U.S. Food and Drug Administration, *New Drug Application*, Promoting Your Health, <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm> (last updated Feb. 21, 2013); *see also* 21 U.S.C.A. § 355 (1982).

¹⁰⁸ 21 U.S.C.A. § 355 (1982).

¹⁰⁹ *Id.*

approval/rejection.¹¹⁰ Once filed with the FDA, the FSIS would receive the a copy of the application, and in return, make suggestions to the FDA on suitability, efficacy, and conditions that would likely need to be followed before allowing particular petitioned drug should be approved.¹¹¹ The FDA then considers the suggestions made by the FSIS and includes those conditions as it sees fit.¹¹²

Typically, a company will submit a New Drug Application (“NDA”) to the FDA for a food additive they would like to start using in their products. Upon receipt, the FDA notifies the petitioner the FSIS, who then receive and review all relevant data with regards to the additive in the petition. The FDA and FSIS then work together over a 60-day period to address the concerns each have with the application. If approved, the FDA then sets the regulations that will accompany the safe use of the additive, taking recommendations from the FSIS in writing.

IV. Moving Forward to Protect Consumers

Determining how to properly monitor and regulate the use of hormones in beef is very complex, as demonstrated by the history of FDA and USDA oversight and congressional measures such as the Delaney Clause. Given this complexity, perhaps it is more efficient to only have one agency, either the FDA or the USDA, be chiefly responsible for the regulation of beef products containing hormones. In addition, the Government should fund more scientific research, conduct more meaningful enforcement of regulations, and provide labeling on beef products sold for consumption.

A) Scientific Research

¹¹⁰ *Memorandum of Understanding, supra* note 1.

¹¹¹ *Id.*

¹¹² *Id.*

The first step to solving our problems is conducting more scientific research. As of right now, the International Agency for Research on Cancer (“IARC”) recognizes four tiers of animal evidence of cancer causing substances; “1) sufficient evidence, 2) limited evidence, 3) inadequate evidence, and 4) evidence suggesting lack of carcinogenicity.”¹¹³ As it stands right now, most of what we know falls in the latter two categories.

As shown in mice and other studies, synthetic hormones have potentially dramatic adverse effects on human health. We must determine with empirical evidence just how much of each synthetic hormone is actually dangerous in human consumption. No longer can the government play a guessing game when the uncertainty of their decisions can pose a risk to human life.

Some advocate that taking a strict conservative approach will ensure this does not happen, but this is not the answer. If the regulators become too strict, every item would have to be removed from grocery stores shelves. The only way to reconcile this problem is to determine conclusively what hormones are harmful and at what levels, then developing capable means of detecting those safe levels. Detection methods have greatly lagged in sensitivity in response to the increasingly smaller amounts of hormones being potentially carcinogenic; therefore regulators must vastly improve detection methods.

Scientific research is extremely hard to collect if you are not paying the scientists yourself to research the questions you want answered. To have this privately done would cost the Government millions of dollars they do not have. Since our Government is more apt to cut funding to both the FDA and USDA, perhaps a better solution may be to give Universities and research intuitions large grants or other financial incentives to pursue studies that can have their

¹¹³ *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans*, IARC Internat. Tech. Rap. No. 87/001, at 30-31 (1987).

questions answered. These financial incentives would be well received by lawmakers, since it is hard to argue against funding for education.

B) Meaningful Enforcement

The second step is diligent (or perhaps “more meaningful”) enforcement of the procedures set forth by the FDA and USDA for testing and penalties. The regulators rely on far too many assumptions when putting their guidelines and rules in place. As shown with the DES case study, barely any testing was conducted, the tests did not use a large enough sample size to reflect the entire meat industry, and tests inadequately measured residues. To top it all off, the FSIS found violations of the regulations every single year.

Farmers should not be allowed to hand pick the cows the FSIS tests for hormone levels, nor should they be allowed to get off with minor fines for non-compliance. We all know we do not live in a perfect world, and using hypothetical theories that assume farmers will adhere to requirements that they could easily circumvent to make themselves more money is both foolish and naïve. Too many farmers will see the financial incentives and completely refuse to follow any regulations, especially when the scientific research is not concrete that the hormones they are using are harmful in the first place.

After the appropriate research is completed and reliable results are found, either the FDA or the USDA must ensure the rules and regulations are enforced. Dual agency enforcement can work, but the USDA should probably have more responsibilities than the FDA. Above all, the Government needs to give either regulatory body the enforcement tools to give farmers the incentive to adhere to the rules. This can be done through fines, on a progressive scale, for the severity of the infraction and repeat offenders. They should also have the ability to threaten

producers with jail time for habitual offenders who intentionally break the rules and put peoples health at risk.

C) Labeling

At the moment many of these solutions would be difficult to implement, so in the mean time there must be a way to appease both the meat producers who want the hormones used, and the public, who want to make sure what they consume, is safe. This can easily be solved with a labeling system. Labeling is the responsibility of the FDA, so it may make sense that they subsume the USDA's responsibilities regarding meat production in the transition period.

As of right now, many items in grocery stores are labeled "Raised Without Added Hormones," "No Hormones Administered," or "No Synthetic Hormones". These labels are placed on pig and poultry products however, where there is no use of hormones allowed in any capacity.

Labeling for beef products should use some of the same terminology. Currently, with the limited technology farmers possess, there should be only two labels. One label could indicate that the producer does administer synthetic hormones, in any capacity, to its cattle. The other label can signify that the producer does not use any synthetic hormones, what so ever. As the technology improves, the labeling can become more sophisticated, perhaps indicating which producers administer high levels of synthetic hormones compared to those producer's animals receiving minimal doses.

These solutions all require increased public awareness. The USDA and FDA need to do a better job of informing the public on the risks of cattle being treated with synthetic hormones. They need to have a proactive approach and allow information to be absorbed by everyone who eats meat. Once this is done, it will give the American public the ability to look at the risks and

rewards of meat consumption, and make an educated decision on what they feel is best for themselves and their families. The public is vulnerable to the unknown, and informing consumers of beef is both the biggest responsibility and one of the biggest challenges facing the FDA and USDA.

Once we have reliable information, getting it to the public should not prove difficult. The FDA and USDA could distribute pamphlets, place information on their respective websites, or even force beef producers to place a label with basic information as to how/what/why they used synthetic hormones, and possible risks. The Government could also provide funding for a marketing campaign, allowing commercials to be run on television discussing basic concerns and risks with hormone treated beef. Every bottle of medication we receive enumerates clearly on the label all possible side effects, why not have meat-packaging labels to the same?

Due to a lack of scientific information, and contradictory results of hormone effects and residual levels all over the world, it is hard to inform the public accurately on the risks of synthetic hormones. So in essence, the only thing the regulatory bodies can do at this point is be overly cautious when advising consumers on meat consumption. Until more reliable information is available, having seen the harmful effects of DES, caution it is the only acceptable route for the government to take.

Misinformation and lack of information can lead to irrational public fear. When there was a rise in early puberty of young women in Puerto Rico, hormones were the alleged culprit; however the science and testing results did not back up the claim. Puerto Rico saw a huge reduction of meat consumption due to the rumors and information being circulated as synthetic hormones as the cause of the early puberty. This led to hundreds of farmers losing profitability, losing their farms, and losing their livelihood.

The United States simply cannot have a similar situation. Meat is an enormous export of the United States, and the less we know about the synthetic hormone use, the easier it is for someone misinformed to blame an epidemic on it. A public hysteria over the safety of American meat would be catastrophic on the market and exports around the world.

CONCLUSION

Synthetic hormones can be incredibly beneficial to the agricultural production of the United States. When used safely, the industry's ability to create more consumable beef per cow while saving money on cattle feed. This creates a great scenario for the American public where there is no shortage of beef and the price per pound vastly decreases. However, with some synthetic hormones being potentially toxic when consumed at certain levels, the Government must do more to ensure that when synthetic hormones are being used, they are both highly regulated and safe for human consumption.

The United States needs to concentrate its efforts on gathering the scientific information necessary to determine the safe levels of hormones that humans can consume. The Government can then ensure the proper levels of hormones are being administered, and allow regulatory bodies to enforce and punish those in the industry that do not adhere to the rules. Implementing stricter testing procedures, and providing labeling on finished meat products, while working with those conducting research to provide reliable information to the public in the meantime is a practical and feasible way for both a short and long term solution to the synthetic hormone dilemma.