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Leticia M. Diaz  
*Barry University*

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# HORMONE REPLACEMENT THERAPY, OR JUST EAT MORE MEAT: THE TECHNOLOGICAL HARE VS. THE REGULATORY TORTOISE

LETICIA M. DIAZ\*

*We are a society advancing towards undetermined levels of technological sophistication. As we enter the new millennium, we bring a wealth of highly advanced biotechnology, allowing the synthesis of chemicals and hormones which are designed to kill or alter living organisms. Unfortunately, we as humans fall into the definition of "living organisms."*

## INTRODUCTION

Women continue to be prescribed hormones throughout their lives for birth control, regulating menses, and combating premenopausal and post-menopausal symptoms. Similarly, the Food and Drug Administration (FDA) continues to approve hormone use for livestock. Is there a correlation between the two, or is it a mere coincidence that women who eat meat and dairy products have more problems regulating their hormones and general health than women who eat a tofu dinner?<sup>1</sup>

Livestock producers inject<sup>2</sup> or feed hormones to their animals to increase weight and the efficiency of feed use.<sup>3</sup> Livestock subjected to

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\* Assistant Professor of Law, Barry University of Orlando School of Law, J.D., Rutgers University School of Law, Newark (1994); Ph.D. (Organic Chemistry), Rutgers University, Newark (1988). Many thanks to my husband Dr. Harry Behzadi, a fellow scientist, for his scientific research and assistance. Much appreciation to Professor Pam Armstrong, Dean Stan Talcott, Johanna Talcott, and Margaret Satterfield for their contributions.

Several comments in this paper are opinions stemming from the author's scientific background and should only be construed as such.

<sup>1</sup> See generally Norine Dworkin, *22 Reasons to Go Vegetarian Right Now: Benefits of Vegetarian Diet*, VEGETARIAN TIMES, Apr. 1, 1999, at 90.

<sup>2</sup> Hormones which are administered for the purpose of increasing growth are given in the form of pelleted hormone implants that dissipate over time. These implants are injected under the skin on the back side of the ear. The ears are then removed when the animal is slaughtered. The ears are not sold as food material for human use. See Jan R. Busboom & Karen P. Penner, *Hormones and Meat* (visited Mar. 4, 2000) <[http://www.inform.umd.edu/EdRes/Topic/AgrEnv/ndd/safefood/HORMONES\\_AND\\_MEAT.html](http://www.inform.umd.edu/EdRes/Topic/AgrEnv/ndd/safefood/HORMONES_AND_MEAT.html)>.

<sup>3</sup> See *id.*

hormones can gain weight faster on less feed than animals not subjected to hormones. The hormone-laden animal is therefore more efficient than its hormone-free counterpart, as it gains weight faster and can be slaughtered sooner.<sup>4</sup> But this efficiency does not come without risk. The issue to be evaluated is who bears this risk. Are women ingesting excess hormones through their food? If so, should the FDA continue to approve hormone use or should it follow Europe's lead in banning beef treated with hormones?

Moreover, Xenoestrogens<sup>5</sup> found in certain pesticides also pose health concerns to women. The Delaney Clause,<sup>6</sup> no longer applicable to pesticides, must be redefined in terms consistent with existing technology, and must be reinstated in order to protect the American population, particularly women, from deleterious chemicals that may cause cancer and certainly wreak havoc on their entire system by creating hormonal imbalances. These imbalances, in turn, lead to an array of systemic upsets.

Some hormones and chemicals that mimic hormones, such as Xenoestrogens, are known as hormone disruptors.<sup>7</sup> Hormones are chemicals excreted into the bloodstream which control many physiological functions of the human system. Extrinsic factors, such as toxic chemicals or added hormones, can block the necessary natural interaction between hormones and human cells, resulting in hormone disruption.<sup>8</sup> Research conducted by Dr. Theo Colborn revealed the correlation between environmental chemicals and their adverse effects on the human endocrine system.<sup>9</sup>

This article explores the interrelationship between human consumption of meat and dairy products treated with hormones and/or exposed to pesticides, and the health risks associated with such consumption. Special attention is given to hormonal upsets unique to women, and to whether the FDA is adequately addressing these issues.

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<sup>4</sup> See *id.*

<sup>5</sup> Xenoestrogens refer to other environmental compounds that generally have very potent estrogen-like activity and thus can be considered very toxic. See JOHN R. LEE, M.D. & VIRGINIA HOPKINS, WHAT YOUR DOCTOR MAY NOT TELL YOU ABOUT MENOPAUSE 41 (1996).

<sup>6</sup> See 21 U.S.C. § 348(c) (3) (A) (West 2000).

<sup>7</sup> See Sam Tucker, *World Wildlife Fund Canada's Guide to Hormone Disruptors*, BOSTON REV., Sept. 9-15, 1996, available at <<http://www.webactive.com/webactive/features/wwfcan.htm>>.

<sup>8</sup> See *id.*

<sup>9</sup> See *id.* The endocrine system is the manner by which hormones are used and distributed by the human body.

Part I of the article discusses the specific hormones approved for use in the United States and the FDA regulatory process for approving such hormones for use in livestock. Part II looks at the ban by the European Economic Community (EEC) on imported hormone-implanted beef and evaluates the implications of that ban, as well as the FDA's response to the ban. Part III addresses the Delaney Clause as it relates to pesticide residue in meat and dairy products, and proposes that the Environmental Protection Agency (EPA) and the FDA take a fresh view of the clause with proposed modifications. Part IV considers the germane health risks, such as Estrogen Dominance and breast cancer, unique to women who eat meat and dairy products either treated with hormones or exposed to pesticides which act as Xenoestrogens in the body. Part V discusses the new organic meat market as an alternative for health conscious consumers. Part VI concludes that the FDA and other governmental regulatory agencies must consider gender concerns prior to approval of certain hormones or pesticides. It also urges that the Delaney Clause must be redefined to create a functional regulatory scheme, consonant with our technological world, to evaluate the exigent health issues related to pesticide use. Health threats unique to women who ingest hormone- or chemical-laden foods are also addressed. Such foods must be studied not only for overall carcinogenic effects, but also for female-specific diseases, particularly those of the female reproductive system. Finally, hormones which have already been approved must be reevaluated for specific determinations of whether these chemicals are causing significant effects on the reproductive systems of both men and women.

#### I. THE FDA APPROVES HORMONES FOR USE IN LIVESTOCK

The FDA Center for Veterinary Medicine (CVM) is responsible for assuring that animal drugs and medicated feeds are both safe and effective for human consumption.<sup>10</sup> A new animal drug, similar to new drugs for human use, must be approved by the FDA prior to entering the U.S. market.<sup>11</sup> Section 360(b) of the Federal Food, Drug,

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<sup>10</sup> See Food & Drug Administration; Statement of Organization, Functions, and Delegations of Authority, 49 Fed. Reg. 10,166, 10,167 (1984); see also U.S. Food & Drug Administration, *A Historical Perspective of CVM* (last modified Sept. 30, 1999) <<http://www.fda.gov/cvm/fda/aboutcvm/beginningstxt.html>>.

<sup>11</sup> See 49 Fed. Reg. at 10,175. The new animal drug must be approved on the basis of quality, safety, and efficacy. With respect to safety, although safety to the animal is impor-

and Cosmetic Act (FFDCA) sets forth the requirements necessary in a New Animal Drug Application (NADA).<sup>12</sup> The testing, processing, and eventual approval of a NADA is a detailed and complicated procedure.<sup>13</sup> Applications are scrutinized for accuracy as well as for scientific data indicating human safety. If a primary reviewer determines that further scientific testing is needed, the submission is forwarded to the appropriate scientific unit.<sup>14</sup> Approval of products does not end the process. The CVM continues to monitor the use of the products to insure compliance with all safety standards.<sup>15</sup> In fact, one of the charges of the CVM is to bring violators of the safety standards into compliance with the law.<sup>16</sup>

Six hormones are endorsed by the FDA for use in increasing the rate of growth of beef cattle.<sup>17</sup> The agency has deemed that only very small amounts of hormones are needed to achieve an increase in the rate of cattle weight gain and to improve feed efficiency in livestock.<sup>18</sup> The hormone-growth drugs are generally administered by livestock

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tant, safety of all food products derived from treated animals that are intended for human consumption must also be demonstrated. *See id.*

<sup>12</sup> *See* 21 C.F.R. §§ 360(b), 514.106 (West 2000). Section 360(b) of the FFDCA requires the FDA to take an appropriate action within 180 days of filing of an NADA. The outline depicting the organization and content of an NADA is governed by 21 C.F.R. section 514.106. *See id.* § 514.106.

<sup>13</sup> *See* Center for Veterinary Medicine, *Program Policy and Procedures Manual, Guide 1240.3010: Processing Original Investigational New Animal Drug Applications* (last modified May 14, 1998) <<http://www.fda.gov/cvm/fda/aboutcvm/3010.pdf>> [hereinafter *Processing Original Investigational New Animal Drug Applications*].

<sup>14</sup> *See id.* Even after the initial review is concluded, team leaders once again check all material for additional assessment. The Division Director then reviews and evaluates the conclusions of both the reviewers and the team leaders. *See id.*; *see also* Center for Veterinary Medicine, *Program Policy and Procedures Manual, Guide 1240.3100: General Review and Enforcement Policies, Initial Processing of an NADA* (last modified May 14, 1998) <<http://www.fda.gov/cvm/fda/aboutcvm/3100.pdf>> (providing further information outlining the steps of processing an NADA).

<sup>15</sup> *See Processing Original Investigational New Animal Drug Applications, supra* note 13.

<sup>16</sup> *See id.*

<sup>17</sup> *See* Patti Goldman & J. Martin Wagner, *World Trade Organization Dispute Settlement Proceeding European Communities—Measures Concerning Meat and Meat Products (Hormones)* (visited Oct. 4, 1996) <<http://www.citizen.org/pctrade/gattwto/Cases&Tribunalists/beef.html>>. Three of the hormones, estradiol-17, progesterone, and testosterone are naturally occurring hormones. The other three, trenbolone acetate, zeranol, and melengestrol acetate (MGA), are synthetic. All the hormones, except for MGA, are administered in the form of pellets implanted in the ears of the animals. MGA is approved for administration directly in cattle feed. *See id.*

<sup>18</sup> *See* Food & Drug Administration Center for Veterinary Medicine, *The Use of Hormones for Growth Promotion in Food-Producing Animals* (May 1996) <<http://www.fda.gov/cvm/fad/infos/hormones.html>> [hereinafter *Use of Hormones*].

producers at various stages of production.<sup>19</sup> Despite continued debate regarding the safety of the hormones, the FDA has determined that residue levels of the hormones found in food are safe and are below levels that pose health risks to humans.<sup>20</sup> On the other hand, the European Union (EU) issued an extensive report concluding that at least one of the six growth hormones contained in U.S. beef exports causes cancer.<sup>21</sup>

Three of the six hormones, estradiol, progesterone, and testosterone, are produced naturally in the bodies of all humans.<sup>22</sup> The safety of using these hormones in livestock is posited on the theory that the hormones are naturally occurring in the human body, and that the human body is exposed to large quantities of hormones through its own daily hormone production. Therefore, according to the FDA, consuming additional but "minimal" residual quantities of hormones from food derived from hormone-laden animals poses no increased health risk to humans.<sup>23</sup>

The other three hormones are not naturally occurring. There is no daily production rate of the synthetic hormones trenbolone acetate, zeranol, and melengestrol acetate (MGA). Approval of these hormones required comprehensive toxicological testing to determine the safety level allowance for these synthetic compounds.<sup>24</sup> There is a question regarding the validity of the tests relied upon by the FDA, given the timing of the approval. For example, implants containing estradiol benzoate and progesterone were first approved by the FDA

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<sup>19</sup> See *id.*

<sup>20</sup> See *id.* The argument in favor of safety is that the amount of the added hormone is negligible compared to the consumer's own daily production rate. See *id.* However, more scientific research is needed to determine whether even levels considered scientifically "negligible" may have an endocrine disrupting effect not only on the endocrine system, but on the human system as a whole.

<sup>21</sup> Letter from Ronnie Cummins, Campaign for Food Safety, to Pure-food-action@mr.net (June 4, 1999) (on file with author). The EU's Scientific Committee on Veterinary Measures told the Associated Press that the hormone 17 beta-oestradiol "has to be considered as a complete carcinogen." *Id.* In addition, the panel stated that all the banned hormones had the capability of causing a host of health problems, even at the small levels found in meat residues. See *id.*

<sup>22</sup> See *Use of Hormones*, *supra* note 18. These hormones are essential for the proper physiological functioning of human body systems. See *id.*

<sup>23</sup> See *id.* The scientific studies allegedly detail that the concentrations derived from these meats remain within the normal physiological range that has been established for like untreated animals of the same age and sex. See *id.*

<sup>24</sup> See *id.* The manufacturers are required to prove that the hormone residues are below this safety level. See *id.*

in 1956.<sup>25</sup> MGA, which is approved as a feed additive, was cleared by the FDA in 1977.<sup>26</sup> Although more updated tests may be underway in light of the dispute regarding the safety of these hormones, the original in-depth toxicological testing is outdated. Given the controversy over how much testing has actually been done to quantify the effects, if any, of residues from these hormones, the United States should employ current scientific techniques to resolve the controversy.

## II. THE EUROPEAN ECONOMIC COMMUNITY BAN AND THE FDA RESPONSE

### A. *The European Community Bans Meat Treated With Hormones*

The EU has suspended imports of beef and bovine liver from the United States, notwithstanding continuing threats by the U.S. government to impose 100 percent tariffs on more than \$900 million worth of European products unless the ban is lifted.<sup>27</sup> The stated purpose of the suspension is to protect consumer health.<sup>28</sup> Inspectors from the EU's Food and Veterinary Office have determined that meat imported from Canada and the United States does not satisfy the EEC's safety standards.<sup>29</sup> The EEC became aware of possible health

<sup>25</sup> See 21 C.F.R. § 522.1940 (1997); see also Dale E. McNiel, *The First Case Under The WTO's Sanitary And Phytosanitary Agreement: The European Union's Hormone Ban*, 39 VA. J. INT'L L. 89, 99 (1998).

<sup>26</sup> See 21 C.F.R. § 558.342; see also McNiel, *supra* note 25, at 99.

<sup>27</sup> See Associated Press, *EU Won't Bend on Beef*, DESERET NEWS, Oct. 5, 1999, at E4. The World Trade Organization (WTO) has stated that the ban is illegal and is not supported by proper scientific risk analysis. The EU disagrees and continues to contend that hormone-laden meat poses health risks to consumers and that at least one of the hormones in dispute has a probability of causing cancer. The FDA and other U.S. governmental entities dispute these findings. See *id.*

The EU is particularly concerned with the fact that 17 beta-estradiol, which they found to exert both tumor-initiating and tumor-promoting effects, as well as the other hormones used in implants, are freely available over-the-counter in the United States. See Barry James, *Battle to Prove Beef Hormone Risk; Behind Contested EU Ban, a Scientific Puzzle*, INT'L HERALD TRIB., Oct. 18, 1999, at 13. The EU is concerned with the lack of supervision involved in administering these hormones. Because the EU alleges there are no U.S. controls in place, a misplaced hormone implant can enter the food supply with a high risk of hormone contamination. See *id.*

<sup>28</sup> See *id.*

<sup>29</sup> See Laura Eggertson, *Meat Checks Deficient, EU Argues*, TORONTO STAR, Oct. 27, 1999, available at <[http://www.thestar.com/back\\_issues/index.html](http://www.thestar.com/back_issues/index.html)>. In a news release, the EU stated that:

[h]uman exposure and risk are in particular increased by the fact that regulatory controls over residues of hormones in meat placed on the market are deficient in the U.S.A. and are insufficient in Canada. There is a clear poten-

issues related to beef containing hormones when European scientists found residues of growth hormones in products from the United States.<sup>30</sup> The residues were found after European scientists conducted an independent study in response to a decision by the World Trade Organization's (WTO) Appellate Body (in January 1998) that the EU ban on hormone-treated beef lacked any scientific basis.<sup>31</sup> The EEC maintained that the ban was necessary to protect the health and safety of its consumers.<sup>32</sup> The EEC's decision to conduct further studies to refute the Appellate Body's response has not been viewed favorably by many. Not surprisingly, cattle exporters in the United States were among the parties who expressed displeasure with the extension of the studies.<sup>33</sup>

The European ban does not exclude all meat products exported from the United States. Beef which is not treated with hormones is welcome to enter the EU despite EU findings of U.S. non-compliance

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tial for adverse effects on human health arising especially from the presence of residues of these hormones.

*Id.*

<sup>30</sup> See *id.*

<sup>31</sup> See *id.* In addition, a Dispute Settlement Panel of the WTO held that the European ban on meat from animals treated with certain growth hormones violated international trading rules. This was not the first conflict of environmental and health concerns and trading rules. Three sets of rules usually apply with respect to the environment and health: (1) GATT 1994 Articles XX (b), (d), and (g), which provide exceptions to other GATT articles; (2) the Agreement on the Application of Sanitary and Phytosanitary Measures, otherwise known as the SPS Agreement; and (3) the Agreement on Technical Barriers to Trade. For purposes of this article, number (2) is the most relevant, as the Settlement Panel determined that: "[b]y maintaining sanitary measures that do not rest on a scientific 'risk assessment,' the EC has acted inconsistently with Article 5.1 of the SPS Agreement." See John R. Schmertz & Mike Meier, *WTO Panel Decision Holds that European Communities' Ban on Meat From Animals Treated with Growth Hormones Violated International Trading Rules*, 3 INT'L L. UPDATE 120, 120-21 (1997). See also David A. Wirth, *European Communities Restrictions on Imports of Beef Treated With Hormones—NonTariff Trade Barriers—Control of Food Additives—Scientific Basis For Restrictions—WTO Dispute Settlement Mechanisms—Scope of Review*, 92 AM. J. INT'L L. 755, 755-56 (1998). "For more than a decade, the United States, where use of the same hormones is permitted for these purposes, has objected to the EC hormone ban as a NonTariff barrier to trade *unsupported by scientific evidence*." Wirth, *supra*, at 755-56 (emphasis added).

<sup>32</sup> See Charles E. Hanrahan, Congressional Research Service, *The European Union's Ban on Hormone-Treated Meat* (Feb. 8, 1996) <<http://www.cnle.org/nle/ag-15.html>>.

<sup>33</sup> See Wirth, *supra* note 31, at 759. The U.S. cattle exporters should have expressed a desire to settle the scientific uncertainty regarding the potential hazards of meat laden with hormones. If exporters are to stand behind their contention that the hormones pose no danger, then they should not only express enthusiasm at research that would resolve the issue, but should in fact lend financial assistance to assist in the expediency and availability of such research. See *id.*



with the no-hormone agreement between the EU and U.S. exporters.<sup>34</sup> That is, the EU continues to allow the import of beef that is certified to be hormone-free, despite recent findings that, in fact, hormone residues were found in such meat.<sup>35</sup> The fact that the EU still allows the import of this beef should take this international issue out of the political arena and place it within the scientific ambit, where it rightfully belongs. If the EU did not have public health interests at heart, it would find a way to ban all meat from the United States, hormone-treated or not. Certainly, a politically motivated EU would have pounced on the discovery that meat labeled hormone-free from the United States was found to contain hormones. Instead, it continues to allow meat labeled as hormone-free into its market while relying on U.S. promises to remedy the problem. In light of the above overture by the EU, the United States should be less critical of the European ban, which cites purely health concerns, and should instead focus on disproving the claims regarding the dangers of meat treated with growth hormones. In doing so, the United States would assure its own citizens, in addition to the Europeans and the rest of the world, that U.S. beef is safe to consume.

#### B. *European Studies—Science or Science-Fiction?*

Are consumers at risk when eating meat from animals that have been treated with growth-promoting hormones? Are women in particular at a higher risk from ingestion of hormone-laden meat? As far as the EU is concerned—yes. Yet, the European community continues to be criticized for trying to protect its citizens from possible adverse effects of consuming such meat products. In fact, the Clinton administration has accused the EU of circulating misleading reports in order to continue to refuse opening its market to meat products from cattle raised on growth hormones.<sup>36</sup> U.S. Agriculture Secretary Dan Glickman and U.S. Trade Representative Charlene Barshefsky are adamant

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<sup>34</sup> See *EU Agrees on Meat Standards*, FOOD INGREDIENT NEWS (Bus. Communications Co.), Aug. 1999. In fact, it is the United States which has just recently voluntarily suspended shipments of "hormone-free" meat to the EU as a result of concern that U.S. meat suppliers were not delivering what was agreed upon. In the Spring of 1999, the EU discovered that twelve percent of the beef labeled as hormone-free contained hormone residues. See *id.*

<sup>35</sup> See *id.*

<sup>36</sup> See Meat Industry Insights News Service, *U.S. Accuses EU of "Misleading" Hormone Report* (May 4, 1999) <<http://www.lihq.net/spc/mii/990530.htm>>.

that the EU study repeats arguments which are unsubstantiated.<sup>37</sup> If the United States is convinced that the EU's scientific data lacks merit, the United States should conduct further studies in order to protect the American consumer, instead of dismissing the EU's provocative claims. In order to accurately assess the validity of the ban, the scientific evidence produced by the EU must be reviewed and scientifically evaluated, not merely dismissed by U.S. policymakers.

In 1999, an official EU scientific panel released a comprehensive report which confirmed that at least one of the six growth hormones contained in U.S. beef products, which are now banned by the EU, conclusively causes cancer.<sup>38</sup> The EU panel further stated that all of the banned hormones are thought to cause a variety of health problems or diseases, including cancer, developmental problems, immunological breakdown, brain disease, and others.<sup>39</sup>

A critical point made by the EU report was that exposure to even small levels of hormone residue in meat and meat products carries a certain magnitude of risk.<sup>40</sup> Those statements completely contradict the U.S. position that unequivocally asserts that the level of hormones remaining in our meat products is too small to be clinically significant.<sup>41</sup>

The findings by the EU that hormones used to promote growth in livestock may promote carcinogenesis is not a controversial scientific "breakthrough." It has been well documented that these types of hormones may stimulate carcinogenesis by acting as a background for tumorigenesis by chemical, physical, or viral agents, or by promot-

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<sup>37</sup> See *id.* The EU report states that excess intakes of the six growth hormones used in cattle production could have an adverse effect on consumer health. In addition, the EU continues to state that one of the hormones, 17 beta-oestradiol, may have a propensity to cause cancer. Both Secretary Glickman and Trade Representative Barshefsky believe the EU report is but a ploy and is a deliberate attempt to ignore scientific data which they believe has proven that these hormones do not pose a risk to human or animal health. See *id.*

<sup>38</sup> See Ronnie Cummins & Ben Lilliston, *Beef Hormones, Irradiation, & Mad Deer: America's Food Safety Crisis Continues*, CENTER FOR FOOD SAFETY NEWS #19 (formerly FOOD BYTES), June 4, 1999, at 1. The EU's Scientific Committee on Veterinary Measures spoke to the Associated Press and stated "the hormone 17 beta-oestradiol has to be considered as a complete carcinogen". *Id.*

<sup>39</sup> See *id.*

<sup>40</sup> See *id.*

<sup>41</sup> See Busboom & Penner, *supra* note 2. The FDA, in studying the effects of hormone residues on human health, determined that if consumers eat meat which contains one percent or less of the amount of hormone their own bodies produce, no ill effect should be expected. See *id.* (table comparing estrogen in meat and estrogen produced daily by humans).

ing the growth and metastasis of tumors once they have been initiated.<sup>42</sup>

Furthermore, these growth hormones are also known to cause dangerous estrogenic effects that have been calculated to be about 10,000 times higher than some banned pesticides.<sup>43</sup> In addition, from 1979 to 1981, approximately 3,000 Puerto Rican infants and children experienced premature sexual development and developed ovarian cysts as a result of elevated levels of estrogen and the synthetic hormone Zeranol in the meat they consumed.<sup>44</sup> There was also an association with an increase in the rates of uterine and ovarian cancers, fibrocystic disease of the breasts, polycystic ovaries, menstrual irregularities, and infertility problems in adult women who consumed these same food products.<sup>45</sup> Interestingly, the clinical signs diminished significantly after diet control.<sup>46</sup>

Further claims that contributed significantly to the ban by the EU were derived from a study indicating that infants who ate food containing the hormone diethylstilbene (DES) developed breasts. The infant girls also began menstruating.<sup>47</sup> Based upon these studies and others, the EU concluded that U.S. beef which was fed or treated with these growth hormones posed a health risk to consumers, and accordingly instituted its ban.

The six controversial growth hormones studied by the Scientific Committee for Veterinary Measures relating to Public Health are 17 beta-oestradiol, progesterone, testosterone, zeranol, trenbolone, and MGA.<sup>48</sup> The study addressed the potential risk arising from the use of

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<sup>42</sup> See Goldman & Wagner, *supra* note 17.

<sup>43</sup> See *id.*

<sup>44</sup> See *id.* The elevated levels of estrogen were found to have been a result of the consumption of meat products which contained elevated amounts of estrogen. See *id.*

<sup>45</sup> See *id.*

<sup>46</sup> See *id.*

<sup>47</sup> See Goldman & Wagner, *supra* note 17. DES was known to cause cancer since 1938. It continued to be used as a growth promoter in livestock, as well as a treatment to prevent miscarriage in pregnant women, until the late 1970s. The detrimental effects on women and their female offspring who ingested this hormone became apparent in the 1960s, when the daughters of women treated with DES started to develop a rare form of vaginal cancer. The United States eventually banned the hormone in 1978.

<sup>48</sup> See European Commission, Directorate-General XXIV, Opinion of the Scientific Committee on Veterinary Measures Relating to Public Health, Assessment of Potential Risks to Human Health from Hormone Residues in Bovine Meat and Meat Products, at 1 (Apr. 30, 1999) [hereinafter E.C. Report]; see also European Commission, *Growth Hormones in Meat Pose Risk to Consumers—Different Levels of Evidence* (May 3, 1999) <<http://europa.eu.int/comm/trade/mitr/dispute/hormones/hor0405a.htm>>. 17 beta-oestradiol, proges-

hormones for growth-promoting purposes in relation to: (a) general concerns related to hormonally active substances evaluating the potential effects of endogenous and exogenous hormone exposure at all stages of life; (b) factors affecting the outcome of exposure to hormones during life span; and (c) hormonal and nonhormonal toxicological effects of endogenous and exogenous hormones and metabolites, taking into account the present state of art in the understanding of biotransformation mediated genotoxicity.<sup>49</sup> The study stated that risk assessment does not necessarily have to arrive at conclusions that only reflect the mainstream of scientific opinion.<sup>50</sup>

The study analyzed the effects of hormones at different stages of life. It fully discussed the experimental methodology and the results of oestrogen<sup>51</sup> exposure on the human system. In analyzing the study, it is evident that the study and its results were based on sound scientific and experimental principles. An interesting issue addressed by the study was that long-term effects of exposure to oestrogenic compounds is not yet known, but that continued environmental exposure of healthy children, even to very low oestrogen levels, might have serious implications.

The epidemiological statistics were both interesting and scientifically convincing. For example, the highest rates of breast cancer were observed in North America, where hormone-treated meat consumption is the highest in the world.<sup>52</sup> Although the report conceded the lack of indisputable confirmation regarding the association between the high rates of breast cancer and the high rates of hormone-treated meat consumption in North America, it was strongly urged that more studies be undertaken to confirm or deny the association.

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terone, and testosterone are natural hormones. Zeronol, trenbolone, and melengestrol acetate are synthetic products. *See id.*

<sup>49</sup> *See* E.C. Report, *supra* note 48, at 3.

<sup>50</sup> *See id.* at 2. The E.C. Report states, in pertinent part, as follows:

[i]t has become evident that equally responsible and representative governments may act in good faith on the basis of what, at a given time, may be a divergent opinion coming from qualified and respected sources. This implies that risk to be evaluated is not only risk ascertainable in a laboratory operating under strictly controlled conditions, but also risk in human societies as they actually exist, in other words the actual potential for adverse effects in human health in the real world where people live and work and die.

*Id.*

<sup>51</sup> The report utilizes the word "oestrogens" to represent compounds of differing chemical structure, which are able to induce histological changes in the vagina and uterus during the estrous (fertile) period. *See id.* at 5-10.

<sup>52</sup> *See id.* at 16.

In light of the fact that breast cancer is generally lower among non-meat consumers, it is evident that the quest for answers must be undertaken in the United States.<sup>53</sup> Other types of cancers showed similar patterns vis-à-vis consumption of hormone-treated meat.<sup>54</sup>

The study further warned that "natural" does not mean "safe."<sup>55</sup> Endogenously produced human hormones such as 17 beta-oestradiol, testosterone, and progesterone cannot be assumed safe at all levels merely based on their natural occurrence. In fact, since a higher risk of breast cancer is associated with certain aspects of women's reproductive life, such as early menarche, women exposed to higher levels of these hormones are more likely to develop cancer.<sup>56</sup> Due to the high exposure to these types of hormones, the crucial question is whether eating hormone-treated meat, even under FDA approved conditions, causes an increased exposure to these hormones which might be significant enough to cause detriment. The study presented calculations that answered that question in the affirmative. Specifically, the investigation concluded that the use of growth-promoting hormones in cattle results in excess daily intakes of these hormones in individuals consuming meat from these cattle.<sup>57</sup>

The study also concluded that there were many safety issues of monumental concern regarding the consumption of meat treated with hormones. The issues under consideration include: (1) neurobiological, developmental, reproductive, and immunological effects; (2) immunotoxicity; (3) genotoxicity; and (4) carcinogenicity. There was

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<sup>53</sup> See *id.* at 17; see also Dworkin, *supra* note 1, at 3. There are, of course, other possibilities for the association between high meat consumption and the increased rate of breast cancer. Other reasons, such as the fat intake from meat may be a factor. However, the association is sufficiently compelling to justify further studies.

<sup>54</sup> It is beyond the scope of this article to present all the scientific findings of the E.C. Report. It suffices to state that the study found positive correlations regarding consumption of hormone-treated meat and illness or hormonal imbalances in humans. See E.C. Report, *supra* note 48, at 16, 17.

<sup>55</sup> See *id.* at 19. Consumers tend to believe that the term "natural" also means "safe." See Leticia M. Diaz, *First St. John's Wort, Now SAM-e: The FDA's Responsibility in Psychiatric Self-Medication: Is Society as a Whole at Risk Without FDA Regulation?*, 9 KAN. J.L. & PUB. POL'Y 283, 285 & n.56 (1999).

<sup>56</sup> See E.C. Report, *supra* note 48, at 21; Cynthia F. Brogdon, *Women and Cancer*, 21(6) J. OF I.V. NURSING 344, 348 (1998). Early onset of menarche is a well established risk factor for developing breast cancer.

<sup>57</sup> The hormone levels presented in the study were determined by radio-immunoassays (RIAS). These assays have been associated with the production of variable results. The study therefore recommends further experimentation in this area. See E.C. Report, *supra* note 48, at 29, 30, 32.

also reference to the fact that no threshold level and no "Allowable Daily Intake" could be established for any of the six hormones.<sup>58</sup>

Overall, the study established correlations using concrete, sound scientific principles. Therefore, the tests and resultant conclusions must be viewed as "true science," not science-fiction. The EU ban is thus well grounded in science and policy concerns about the health of Europeans, rather than on economic or profiteering motives. In the interest of protecting America's public health, the United States must conduct further studies to definitively determine the safety of the six growth hormones presently approved for use by the FDA.<sup>59</sup> The United States cannot moot the safety issue with circular arguments delineating that, inasmuch as three of the hormones are natural, they are therefore safe, and the others are present in concentrations too low to present safety concerns. In fact, the natural growth hormones present unique analysis problems. Unlike synthetic hormones, which can at least be measured, residues of natural hormones may not be detectable because they cannot be differentiated from the same hormones produced by the human body.<sup>60</sup> In addition, undetectable does not equal harmless.<sup>61</sup> Albeit natural, these hormones are nevertheless present, and pose a threat to the delicate balance of the endocrine system. Any residue from hormone-treated meat, natural or synthetic, may create a synergistic or additive effect and should be evaluated thusly. Americans must have a food supply devoid of uncertainties as to their own health risks. Regulatory agencies have the best scientific technology at their fingertips. Embryonic chemical analysis is no longer the norm. Given the specificity with which compounds can be identified, the United States has a duty to put safety concerns to rest.

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<sup>58</sup> See *id.* at 72-73.

<sup>59</sup> Monitoring for hormone residues is done by the Food Safety and Inspection Service and the U.S. Department of Agriculture. Violations are determined by tolerance levels set by the FDA. No monitoring is performed for naturally occurring hormones, based on the FDA's conclusion that the increased exposure to the hormones is far below concentrations considered to be unsafe. See Karen P. Penner, *Hormones and Meat: Food and Nutrition—The Link Between Agriculture and Health* (visited Mar. 4, 2000) <<http://www.foodsafety.org/sf/sf083.htm>>.

<sup>60</sup> See generally Samuel S. Epstein, *The Chemical Jungle: Today's Beef Industry*, 20 INT'L J. HEALTH SERV. 278 (1990).

<sup>61</sup> There is evidence that even exceedingly low levels of industrial chemicals can cause damage through an additive effect. Dr. Ana Soto at Tufts University combined ten hormone disruptors, each at one-tenth of the dose which would be required to produce a minimal response. The results of the experiment indicated that the combination of minute quantities of the chemicals produced a response. See generally THEO COLBORN, *OUR STOLEN FUTURE* (1997); *Our Stolen Future, Part 3: Flying Blind*, Rachel's Env't & Health Weekly No. 490 (Apr. 19, 1996).

Until then, the FDA should recall or, at a minimum, limit the use of these hormones.

*C. The FDA and Other U.S. Responses to the EU Ban*

The FDA and other governmental agencies remain adamant in their position that the EU ban is a political ploy. Gary Weber, Director of Regulatory Affairs for the National Cattlemen's Beef Association (NCBA) has insisted that the ban is not related to safety issues regarding meat and poultry imports.<sup>62</sup> He has consistently maintained that government testing has determined that any hormone residues which may exist do not pose health risks.<sup>63</sup> Canada fully agrees with the United States that further scientific studies are not needed since present studies have clearly concluded that beef treated with growth hormones does not pose a health risk to consumers.<sup>64</sup>

FDA Commissioner Jane Henney stoutly defended the six hormones that have been banned by the EU.<sup>65</sup> In a June 17, 1999 letter to the EEC, Henney stated that expert panels have affirmed the United States's position that meat and meat products from cattle treated with these hormones, when used with good veterinary practice, are safe for consumers.<sup>66</sup> Ms. Henney also responded to the EEC's concerns regarding the carcinogenic potential of estradiol, one of the hormones in dispute. Again, Henney reiterated that it is the FDA's position that a large body of scientific evidence substantiates that estradiol does not pose a cancer risk.<sup>67</sup>

Other U.S. agencies have feverishly taken the same stance as the FDA, expressing displeasure and impatience with the European ban.<sup>68</sup> Tim Galvin, Administrator of the U.S. Agriculture Department's Foreign Agriculture Service has stated that time has run out not just on

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<sup>62</sup> See *EU Proposes Ban of U.S. Meat and Poultry* (visited Oct. 15, 1999) <<http://hill.beef.org/ft/eupbism.htm>>. Weber claims that the ban is a political move to protect the European meat industry. See *id.*

<sup>63</sup> See *id.*

<sup>64</sup> See Meat Industry Insights News Service, *U.S. Says EU Beef Ban Could Damage WTO* (Mar. 13, 1998) <<http://www.pb.net/spc/mii/980329.htm>>.

<sup>65</sup> See *Food Chem. News* (Food Chem. News, Inc., Wash., D.C.), June 21, 1999, at 1.

<sup>66</sup> See *id.*

<sup>67</sup> See *id.* One of the FDA's main arguments is that the European Commission has ignored epidemiological studies performed on women which indicated that estradiol is not genotoxic. See *id.*

<sup>68</sup> See Barry James, *Trade War Looms Over Hormone Beef Ban as EU Reiterates Health Fears*, INT'L HERALD TRIB., May 13, 1999, at 5.

the issue of the ban, but on U.S. patience not to impose tariffs.<sup>69</sup> According to Galvin, four decades of testing has proven "that there is essentially no safety difference between eating beef from animals treated with hormones and those not treated with hormones."<sup>70</sup> The NCBA, not surprisingly, has also expressed displeasure over a ban it deems unfair.<sup>71</sup> George Swan, President of the NCBA, asserted that the EU is not playing fair because the ban results in lost sales of about five hundred million dollars per year.<sup>72</sup>

U.S. trade officials have also repudiated the EU findings, ascribing political and economic motives to the EU ban.<sup>73</sup> The Society for Endocrinology has conveniently reported that "most" scientists do not believe there is credible evidence demonstrating possible health risks to consumers who eat hormone-implanted beef.<sup>74</sup> However, other endocrinologists do suspect that there may be ill effects from hormonal residues. For example, Dr. Niles Skakkebaek, a pediatric endocrinologist at Rigshospitalet University in Copenhagen, Denmark, is not convinced that hormone-laden food has not been a hidden culprit of some hormonal disorders.<sup>75</sup> He is concerned with the growing trend of problems with male reproductive health, and will not rule out the possible role that hormones in food may play.<sup>76</sup> In addition, Dr. Skakkebaek has stated that it is a well accepted theory that breast cancer is hormone-dependent, and that the high incidence of breast cancer among American women should be studied for hormone-related correlations.<sup>77</sup>

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<sup>69</sup> See *id.* ("U.S. impatience on the issue has been 10 years in the making and time has run out").

<sup>70</sup> *Id.* The operative word may be "essentially." Consumers have the right to choose not to take the chance on "essentially no safety difference," and instead to opt for hormone-free meat, which would eliminate even so-called negligible risks.

<sup>71</sup> See *id.*

<sup>72</sup> See *id.* About ninety percent of U.S. beef cattle is treated with hormone implants. It is mathematically obvious why the NCBA is suffering such pecuniary losses. See *id.*

<sup>73</sup> See James, *supra* note 68, at 5.

<sup>74</sup> See *id.*

<sup>75</sup> See *id.*

<sup>76</sup> See *id.* (for example, Dr. Skakkebaek states that "[s]mall boys produce very low quantities or perhaps even none of the female sex hormone, and that means they could receive from treated meat quantities of estrogen perhaps hundreds of times in excess of the amount suggested by U.S. guidelines").

<sup>77</sup> See *id.* Dr. Skakkebaek balks at the U.S. data espousing the safety of hormone residues in meat. He feels that the studies are unreliable because they were developed almost two decades ago. He also rebuts Washington's assertion that hormone residues pose no health hazard, as he claims there have been almost no concrete studies on the extent to which synthetic hormones are absorbed by the human body. See *id.*



The FDA has yet to comprehensively rebut the allegations regarding the carcinogenic/hormonal effects of the six growth hormones at issue. Caroline Smith Dewaal, the Director of Food Safety at the Center for Science in the Public Interest in Washington, D.C., has expressed doubts regarding the assurances of safety. Although she asserted that hormones are cleared from an animal prior to slaughter, she conceded that the levels of the residues in the meat are not monitored.<sup>78</sup> The method of ending this debate is obvious and rudimentary. The FDA must come forth with concrete scientific evidence demonstrating the safety of the growth hormones to a degree of substantial scientific certainty that will assure the public that the meats they eat are safe. Until the United States can conclusively assure both the international community and the American public of the complete safety of hormone-laden meat, the debate will continue. Agencies must keep in mind that science is complex and that different scientists can come to dissimilar conclusions. The only way to resolve a debate based on science is with more science, not words, and today the science is certainly accessible.

### III. REVIVING THE DELANEY CLAUSE WITH UPDATED TECHNOLOGY MAY SOLVE THE HORMONE/PESTICIDE CONTROVERSY

#### A. *History of the Delaney Controversy*

While the above discussion centers primarily on hormone residues in meat, other chemical residues found in our food supply pose the same or possibly even greater dangers. Chemical overload, whether in the form of hormone residues in meat or carcinogenic chemicals ubiquitous in our environment, has been a cause of concern for many decades. Congressman Delaney attempted to respond to consumer demand for a safer food supply.<sup>79</sup> What began as a tiny piece of legislation has sparked a controversial debate that still continues after forty years. The Delaney Clause, introduced by New York Representative James J. Delaney in 1958, was intended to protect the public against any and all carcinogens in chemicals which might find their way into the nation's food supply.<sup>80</sup>

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<sup>78</sup> See James, *supra* note 68, at 5.

<sup>79</sup> See generally Donna U. Vogt, *The Delaney Clause Effects on Pesticide Policy*, Congressional Research Service, Report for Congress, July 13, 1995.

<sup>80</sup> See *id.* The Delaney Clause is codified in the Federal Food, Drug, & Cosmetic Act. See 21 U.S.C. §§ 348, 409(c)(3)(A), 706(b)(5)(B), 512(d)(1)(H) (West 2000). Section 348 states that: "[n]o additive shall be deemed to be safe if it is found to induce cancer when

Representative Delaney chaired a House Select Committee to investigate the use of chemicals in food after the FDA approved a known carcinogen for use as a food additive.<sup>81</sup> Witnesses testified in support of the Delaney Clause, which stated that the lack of technologically feasible scientific methods made it impossible to determine a safe level of any carcinogen in the food supply.<sup>82</sup> Due to this lack of scientific sophistication, the overwhelming consensus was that all carcinogens should be banned from the food supply. The result was a policy which established a zero-tolerance threshold for carcinogenic food additives and pesticides.<sup>83</sup>

The EPA is responsible for the regulation of pesticides. The two major statutes under which the EPA functions in this regard are the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA),<sup>84</sup> and the Federal Food, Drug, and Cosmetic Act (FFDCA).<sup>85</sup>

FIFRA's most important role is the registration system it requires for all pesticides used in the United States.<sup>86</sup> Specifically, a pesticide may not be sold if it has not been registered with the EPA. To become registered, a proposed pesticide must undergo an extensive application procedure.<sup>87</sup> However, the EPA administrator (Administrator) has almost no discretion in denying the application if the required information is submitted, the labeling is correct, and the Administrator deems that the pesticide will not cause "unreasonable adverse effects on the environment."<sup>88</sup> In deliberating the "adverse effects" decision, the Administrator employs a risk-benefit analysis, balancing the benefit obtained from the use of the pesticide against the effect of the pesticide on human health and the environment.<sup>89</sup> If this risk-benefit

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ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal." *Id.* § 348.

<sup>81</sup> See generally Vogt, *supra* note 79.

<sup>82</sup> See *Food Additives: Hearings Before a Subcommittee of the House Committee on Interstate and Foreign Commerce*, 85th Cong., 1st & 2nd Sessions 171 (1958); Andrew J. Miller, Note, *The Food Quality Protection Act of 1996: Science and Law at a Crossroads*, 7 DUKE ENVTL. L. & POL'Y F. 393, 395 (1997).

<sup>83</sup> See Miller, *supra* note 82, at 395-96.

<sup>84</sup> See 7 U.S.C. § 136 (1999).

<sup>85</sup> See 21 U.S.C. §§ 301-395 (West 2000).

<sup>86</sup> See 7 U.S.C. § 136a.

<sup>87</sup> The registration application must contain a statement of claims about the pesticide's proposed use, the data upon which the claims are based, the pesticide's chemical formula, and a request for classification. See *id.* § 136a(c)(1).

<sup>88</sup> *Id.* § 136a(c)(5)(C).

<sup>89</sup> See generally Vogt, *supra* note 79.

analysis is not applied uniformly to all aspects of pesticide use, the result will cause enormous problems due to ensuing inconsistencies.<sup>90</sup>

Whereas FIFRA is responsible for the regulation of pesticide use, pesticide residues in food are regulated under the FFDCA. Under the ambit of the FFDCA, the EPA establishes "tolerances"<sup>91</sup> for any chemical residue that may be left in food products. If the Administrator does not approve a tolerance, and the food contains a pesticide residue, the food is said to be "adulterated," and may not be distributed to the public.<sup>92</sup> Prior to the passage of the Food Quality Protection Act (FQPA), the two sections of the FFDCA were irreconcilable. FFDCA section 408 regulated residues in raw food and provided that the Administrator set tolerances for residues "to such extent he finds necessary for the protection of public health," taking into consideration "the other ways in which the consumer may be affected by the same or by other poisonous or deleterious substances."<sup>93</sup> This language is similar to the language under FIFRA, where a risk-benefit test is employed. The introduction of section 409 of the FFDCA, which applied to pesticide residues in processed food, resulted in contradictory results from section 408.<sup>94</sup> Section 409 regulated food additives and pesticide residues,<sup>95</sup> which were considered food additives until the passage of the FQPA. Unlike section 408, section 409 did not contain a provision for the use of a risk-utility type of balancing test.<sup>96</sup> Section 409 did require the Administrator to establish "safe" tolerances for residues in processed food. In order to set the tolerances, the Administrator was to consider cumulative exposure to residues and other safety factors.<sup>97</sup>

The Delaney Clause can be considered as an attempt to define a test for establishing a "safe tolerance" under section 409 of the FFDCA.<sup>98</sup> Thus, the clause essentially impacted the entire pesticide

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<sup>90</sup> *See id.*

<sup>91</sup> *See* 21 U.S.C. § 346(a) (West 2000).

<sup>92</sup> *See id.* § 342(a).

<sup>93</sup> *Id.* § 346.

<sup>94</sup> *See id.* § 348.

<sup>95</sup> *See id.* § 342(a). It was not necessary for all pesticide residues in processed foods to be assigned tolerances under section 409. Under the FFDCA's "flow-through" provision, if a residue was from a pesticide which was applied prior to processing, there was no need for a section 409 tolerance. *See id.*

<sup>96</sup> *See* 21 U.S.C. § 342(a).

<sup>97</sup> *See id.* § 348(c) (3) (A).

<sup>98</sup> *See id.* The Clause reads in part "no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are

industry. A plain reading of the clause made it clear that a zero-tolerance test was to be applied under section 409. If, under section 409, a pesticide showed any carcinogenic activity, it would be barred. This became quite problematic because under its coordination policy, the EPA refused to set a section 408 raw food tolerance for a chemical that failed under section 409.<sup>99</sup> The net effect was that if a pesticide was deemed even one percent carcinogenic, it would also not be registered by the EPA under FIFRA.<sup>100</sup> Therefore, the Delaney Clause was not only controlled under the FFDCA, but invaded FIFRA's jurisdiction as well.

The regulatory inconsistencies stemming from the implementation of the Delaney Clause came to be known as the "Delaney Paradox."<sup>101</sup> As stated previously, under FIFRA, a tolerance is allowed for a pesticide on a raw agricultural commodity if the benefits of its use outweigh any risks. Thus, under this regulatory act, a risk-utility test is employed, and where the utility is greater than the risk, the EPA will register the pesticide for use. The opposite result occurs under the Delaney Clause pursuant to the FFDCA. Under Delaney, if any new pesticide concentrate in processed food is found to cause cancer at any level, it is disallowed. Thus, under the FFDCA, there was an absolute ban of any possible cancer-causing agent, albeit negligible, whereas, under FIFRA, the negligible effect of the same possible cancer-causing agent would be approved.

The conflict between the FFDCA and FIFRA threw the regulatory system into disarray. As a result, the EPA requested the National Research Council (NRC) to investigate the impact and efficacy of the

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appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal." *Id.*

<sup>99</sup> Under the EPA's coordination policy, the Agency would not grant a section 408 raw food tolerance if the pesticide residue failed section 409's zero-tolerance test. *See* Pesticides; Request for Comment on Petition to Modify EPA Policy on Pesticide Tolerances, 58 Fed. Reg. 7470, 7473 (1993); Pesticide Tolerances; Proposed Revocations, 61 Fed. Reg. 8174, 8174 (1996). The public policy reasoning was probably to avoid massive confusion in the market. Agricultural workers would not know whether a pesticide would be allowed unless they knew to a certain specificity if their crops would be sold as a raw commodity or in a processed food.

<sup>100</sup> *See* Section 409 Tolerances; Response to Petition Requesting Revocation of Food Additive Regulations, 55 Fed. Reg. 17,560, 17,562 (1990). For an excellent review of the Delaney conflict or paradox, see Edward Dunkelberger & Richard A. Merrill, *The Delaney Paradox Reexamined: Regulating Pesticides in Processed Foods*, 48 FOOD & DRUG L.J. 411, 430-38 (1993).

<sup>101</sup> *See id.* at 411.

Delaney Clause with regard to pesticide regulation.<sup>102</sup> The NRC reported that the Delaney Clause was not the most effective way to reduce the risk of carcinogens from pesticide residues in the food supply.<sup>103</sup> Instead, the NRC recommended a "negligible risk standard" for pesticide residues.<sup>104</sup>

The EPA was quick to respond to the recommendations, announcing in 1988 that it would begin to apply a *de minimis* exception to the Delaney Clause.<sup>105</sup> The EPA's ruling was short-lived. In *Les v. Reilly*,<sup>106</sup> the Court of Appeals for the Ninth Circuit struck down the EPA's "*de minimis* exception," finding that the language of the Delaney Clause was unambiguous and that the EPA had abused its discretion. In addition, the Ninth Circuit favorably cited the D.C. Circuit's decision in *Public Citizen v. Young*, which concluded that a *de minimis* exception to the clause was "contrary to law" for the same reasons.<sup>107</sup>

The *Les v. Reilly* decision sparked a movement by industry to pressure Congress to act. After deliberating for several years and reviewing numerous proposals, Congress passed the Food Quality Protection Act.<sup>108</sup> The FQPA amends both FIFRA and the FFDCA.<sup>109</sup> The FQPA did not change the zero-tolerance threshold of the Delaney Clause for food additives, but it cleverly removed pesticide residues from Delaney's ambit by changing the definition of food additive to exclude any pesticide chemical residue.<sup>110</sup> As a result, food additives are still measured by the zero-tolerance threshold for safety, but pesti-

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<sup>102</sup> See *Uniform Standards Recommended to Reduce Potential Cancer Risk From Pesticide Residues*, THE NAT'L ACAD. NEWS (The Nat'l Acad., Wash., D.C.), May 20, 1987, at 3.

<sup>103</sup> See *id.* at 1.

<sup>104</sup> See *id.*

<sup>105</sup> See Regulation of Pesticides in Food: Addressing the Delaney Paradox Policy Statement, 53 Fed. Reg. 41,104, 41,110 (1988).

<sup>106</sup> See 968 F.2d 985, 988-89 (9th Cir. 1992). The court made it clear that, under the Delaney Clause, the EPA had no discretion to allow the use of any food additives, including pesticides that were known to be carcinogenic in nature. See *id.* at 988. It felt that the legislative history was clear and left no room for interpretation. See *id.* The EPA, in turn, argued that a *de minimis* exception to the Delaney Clause was a necessity to allow for a more logical application of the regulatory scheme. The court flatly repudiated this line of reasoning. See *id.* at 990.

<sup>107</sup> See *Public Citizen v. Young*, 831 F.2d 1108, 1123 (D.C. Cir. 1987); *Les*, 968 F.2d at 988-89.

<sup>108</sup> See Food Quality Protection Act of 1996, Pub. L. No. 104-170, 110 Stat. 1489 (codified as amended in scattered sections of 7 U.S.C. and 21 U.S.C.).

<sup>109</sup> An example is the Act's revision of FIFRA's reregistration process. See 7 U.S.C. §136a-1(g)(2)(E) (1999).

<sup>110</sup> See 21 U.S.C. § 3210(s)(1) (1999).

cides, even in food residues, are subject to the risk-benefit balancing test.

Has society benefited from the passage of the FQPA, or are we now in "Chemical Overload?" Although the Act on its face performs seemingly adequate risk assessments regarding a pesticide's potential risk,<sup>111</sup> was society better off with the zero-tolerance standard? "Science is inherently an uncertain art. Humans react differently when exposed to certain toxins. Once a risk assessment is performed, the operative word becomes risk. This is not necessarily a bad concept, yet it is a concept with many loopholes."<sup>112</sup>

When Representative Delaney introduced his bill, he was under the impression that zero-tolerance would mean an absolute abolition of all cancer-causing pesticides. But Representative Delaney did not have the benefit of today's technology. Americans were thus given a false sense of security that their pesticides would not cause cancer. The technology needed to detect small concentrations did not yet exist, and accordingly potentially harmful pesticides could have passed muster under the Delaney Clause and made their way to the supper table.

Perhaps the removal of pesticides from the Delaney Clause was not the safest way to go. The Clause could be redefined to a uniform standard, rather than an across-the-board zero-tolerance. This would also allow food additives which may offer potentially beneficial effects to reach consumers just as fast as the pesticide residues do.<sup>113</sup>

B. *Advanced Technology Allows for a Novel Hybrid Delaney: "Essentially Zero Rather Than Zero"*

The capacity of FDA regulatory officers to inspect and measure all types of potentially harmful residues is dependent upon the capability and sophistication of analytical instrumentation. As such, the sensitivity of the analytical methods chosen or available must be addressed when enforcing or implementing regulations. Advancements in analytical chemistry now allow scientists to uncover residues where

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<sup>111</sup> See EPA Office of Pesticide Programs, *Highlights of the Food Quality Protection Act of 1996* (last modified Aug. 19, 1999) <<http://www.epa.gov/oppfead1/fqpa/fqpahigh.htm>>.

<sup>112</sup> *Id.*

<sup>113</sup> See generally Leticia M. Diaz, *Sucralose: The Sugar of the New Millennium—FDA's Role: A Hindrance or a Help*, 34 NEW ENG. L. REV. 363 (2000).

none were thought to exist, thus requiring the regulatory agencies to take action and set more stringent limits.<sup>114</sup>

Analytical techniques over the decades have increased by at least several orders of magnitude since the 1950s.<sup>115</sup> The most dramatic improvements in analytical chemistry have occurred in laboratory instrumentation methods for detecting pesticide residues.<sup>116</sup> In the 1950s, microgram quantities of the pesticide could be reported using available technology, such as colorimetric determination of pesticides in sample assays.<sup>117</sup> That means that concentrations of pesticides below microgram quantities were reported "non-detected," or in lay terms, "zero." This, of course, lured scientists into a false sense of security that the food sample tested was quantitatively free of harmful residues.

The development of gas chromatography<sup>118</sup> in the 1950s was a breakthrough in instrumentation and experimentation techniques in analytical chemistry.<sup>119</sup> Original gas chromatographs used flame ionization or thermal detectors.<sup>120</sup> The sensitivity of these detectors still allowed only detection of low milligram quantities of pesticides.<sup>121</sup> The development of the Electron Capture Detector (ECD) revolutionized the analysis of pesticide residues; now scientists were able to measure chlorinated pesticides, such as DDT and Chlordane, in picogram ranges.<sup>122</sup> With advances of gas chromatographs equipped with ECD detectors, along with more sophisticated clean-up techniques, scientists are now able to detect more harmful pesticides in food than previously detected.

As technology matures toward more sophistication, agencies find themselves in a quandary trying to keep abreast of the technological

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<sup>114</sup> If agencies determine that more stringent limits should not be set, then, at a minimum, an explanation of the safety of the detected residues should be made public.

<sup>115</sup> See COMMITTEE ON AGRIC., NUTRITION & FORESTRY, *FOOD SAFETY: WHERE ARE WE?* 171 (1979).

<sup>116</sup> See *id.* at 172.

<sup>117</sup> See *id.*

<sup>118</sup> Gas Chromatography is chromatography "in which the moving phase is a mixture of gases or vapors, which separate during their differential absorption by a stationary phase." COMPACT AM. MED. DICTIONARY 183 (1998). In lay terms, this simply means that the organic compounds are able to be separated, identified, and quantified.

<sup>119</sup> See Mark S. Lesney, *From WWII to the Cold War: Through the Eye of the Atom*, ANALYTICAL CHEMISTRY, Mar. 1999, at 45; *Made to Measure, A History of Analytical Instrumentation*, ANALYTICAL CHEMISTRY, Mar. 1999, at 121 [hereinafter *Made to Measure*].

<sup>120</sup> See *Made to Measure*, *supra* note 119, at 121. The specific mechanisms of these type of detectors are beyond the scope of this paper. Interested parties are referred to the citation.

<sup>121</sup> See *id.*

<sup>122</sup> See *id.*

sophistication without upsetting the entire regulatory format. The EPA is in the process of adopting a new policy regarding the use of pesticides in foods which do not result in residues.<sup>123</sup> The policy would set forth criteria for the EPA to consider in evaluating whether a tolerance for a pesticide is needed where the use pattern of the pesticide previously would have been presumed to have left residues in food.<sup>124</sup> The new policy adopts an "essentially zero risk" factor. Under this new policy, no tolerances or tolerance exemptions would be necessary under the FFDCA if:

- (a) using a reliable and appropriately sensitive analytical method to measure residues in the commodity, no residues are detected in the commodity under expected conditions of use when the commodity enters interstate commerce; and
- (b) using reasonably protective criteria, the estimated potential risk of any theoretically possible residues in food is not of concern.<sup>125</sup>

Even if a pesticide were to meet this criteria, it may still be excluded from the exemption if new evidence determines that it no longer qualifies for a no-tolerance classification.<sup>126</sup>

At first glance, this new proposal appears to be a metabolite of the Delaney Clause. However, Delaney was clear that if the pesticide was even suspected of acting as a carcinogen, it would be disallowed. Although pesticides were removed from the Delaney Clause by the passage of the FQPA, it is important to keep the legislative intent of the Delaney Clause in mind.<sup>127</sup> It is equally important to be aware that "undetected" does not equal "nonexistent." Therefore, while the EPA is to be commended for attempting to keep abreast of technology in implementing new regulatory reforms, there are still some pitfalls with the new "Threshold of Regulation Policy." The policy still calls for a risk-utility type of analysis, as the aggregate effect of pesticide residues must be considered. Once a risk-utility analysis is employed, "risks" remain part of the equation.

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<sup>123</sup> See generally Pesticides; Science Policy Issues Related to the Food Quality Protection Act, 63 Fed. Reg. 67,063 (1998); *Threshold of Regulation Policy—Deciding Whether a Pesticide With a Food Use Pattern Needs a Tolerance* (Oct. 18, 1999) <<http://www.epa.gov/fedrgstr/EPA-PEST/1999/October/Day-27/6042.htm>> [hereinafter *Threshold of Regulation Policy*].

<sup>124</sup> See *id.*

<sup>125</sup> *Id.* The EPA would regulate pesticides that qualify under FIFRA. See *id.*

<sup>126</sup> See *id.*

<sup>127</sup> See generally Vogt, *supra* note 79.



The intent of the Delaney Clause was to eliminate all risks and allow Americans to be assured of a "no carcinogenic" food supply. Under the new policy, if residues are not detected but are suspected, the test becomes whether using reasonably protective criteria,<sup>128</sup> the estimated potential risk from any theoretically possible residues in food resulting from such use is "essentially zero," not "zero."<sup>129</sup>

The EPA sets forth a seemingly convincing rationale for the implementation of the "Threshold of Regulation Policy." The EPA contends that the policy would allow for agency resources to be made available for pre-market review of safer pesticides to replace pesticides that do not meet the new safety standard for tolerances established under the FQPA.<sup>130</sup> In theory, the new policy appears to guarantee a safer food supply.

But many issues remain to be addressed. Does undetectable always mean safe? Shouldn't all pesticides with carcinogenic effects be banned, rather than analyzed for residue effects of such pesticides? Although the economic implications of banning all potentially carcinogenic pesticides may appear monumental, the cost of treating a cancer-laden population is equally insurmountable. Using the rationale that the new millennium brings a wealth of new scientific knowledge and analytical advancements, sensitivities of the instruments should be used to ban all carcinogenic pesticides. The focus should not remain solely on the residues, as a minuscule amount of a chemical may exert carcinogenic or hormonal imbalance on the human system. Scientific results are never absolute, and therefore any risk component remains unacceptable.

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<sup>128</sup> See *Threshold of Regulation Policy*, *supra* note 123, at 7. The policy states that:

[r]easonably protective criteria means that incremental risk from exposure to potential residues in food resulting from use of a pesticide should generally be less than 1/1000 of the acceptable risk. The incremental potential risk from the use of a potentially carcinogenic pesticide should be below  $1 \times 10^{-9}$  for a pesticide that exerts threshold effects. Reasonably protective criteria means that the incremental acute or chronic potential exposure from the use occupies less than 0.1% of the acute or chronic population-adjusted dose for the pesticide. EPA will consider potential risks to the most sensitive population, including an appropriate additional safety factor for infants and children as required by the FQPA.

*Id.*

<sup>129</sup> See *id.* at 7.

<sup>130</sup> See *id.* at 2.

#### IV. ESTROGEN DOMINANCE, XENOESTROGENS, AND OTHER HEALTH RISKS UNIQUE TO WOMEN

The above discussion has shed light on the dangers lurking in our food supply due to synthetic hormones and chemicals, as well as our limited ability to measure and make risk assessments taking account of conflicting policy concerns regarding how much risk is too much. But a crucial dichotomy exists. Pesticides, although potentially dangerous and sometimes fatal, provide significant benefits to society. Pests that threaten crops are controlled by pesticides. These overall benefits extend to society through an increase in crop yields, leading to more agricultural growth and an increase in the abundance of food, resulting in lower food prices. Much of the food that is controlled by pesticides is necessary to the human diet.<sup>131</sup> Along with benefits afforded by the availability of foods necessary for the balanced diet come the evil effects of pesticides. One class of pesticides is especially useful in illustrating this dichotomy. Organochlorine compounds, more commonly known to the American public as DDT,<sup>132</sup> has long been the center of controversy for its unique ability to make its home in human fat tissue. Although DDT has been banned for use in the United States, the properties of the chemical, particularly its stable nature, continue to raise health concerns regarding the potential for an increase in carcinogenic risk.<sup>133</sup>

Another area of great concern has been in the estrogen-like activity of chlorinated compounds such as DDT, and their potential causal link to breast carcinoma.<sup>134</sup> As recently as 1999, there was a reported association among women with high levels of the pesticide Dieldrin in their blood system and a greater risk of breast cancer.<sup>135</sup> Women with

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<sup>131</sup> See *Nutrition and Your Health: Dietary Guidelines for Americans* (last modified Nov. 1990) <<http://www.medscape.com/govmt/DHHS/patient/DietaryGuidelines.html>>. For example, vegetables, fruits, and grain products are important parts of a varied diet according to the dietary guideline. See *id.*

<sup>132</sup> DDT is the abbreviation for Dichlordiphenyltrichloroethane.

<sup>133</sup> See generally N. KRIEGER ET AL., *Breast Cancer and Serum Organochlorines: A Prospective Study Among White, Black, and Asian Women*, J. NAT'L CANCER INST. 589-99 (1994). Carcinogenic risk is estimated by the EPA as the incremental probability of an individual developing cancer over a lifetime as a result of exposure to the potential carcinogen. See generally *id.*

<sup>134</sup> See generally *id.*

<sup>135</sup> See Bonnie Liebman, *Pesticides and Breast Cancer* (Mar. 1999) <[http://www.cspinet.org/nah/3\\_99/pesticides.htm](http://www.cspinet.org/nah/3_99/pesticides.htm)>.

higher levels of Dieldrin were twice as likely to develop breast cancer than women with lower levels.<sup>136</sup>

The above-referenced enigmas are indicative of chemicals and hormones which are classified as "Endocrine Disruptors."<sup>137</sup> There are numerous human health effects which have been directly attributed to Endocrine Disruptors.<sup>138</sup> One well-known chemical that has caused adverse reproductive effects in men and adverse carcinogenic effects in daughters of women treated during their pregnancy is the infamous Diethylstilbestrol (DES).<sup>139</sup> Although the deleterious effects of DES were finally uncovered, it is still a mystery as to which chemicals, at what concentrations, and to what extent, cause interference with the endocrine system.<sup>140</sup> The extent of the adverse effects of these Endocrine Disruptors is also unknown. An overabundance of chemicals that act as Endocrine Disruptors can mimic the body's own natural hormones, causing the body to over-respond to the hormone. In the alternative, a chemical may block the effects of a hormone in parts of the body which may normally be sensitive to the chemical. The United States is quite aware of the concerns raised by Endocrine Disruptors. For example, the EPA has already banned the use of many chemicals that raised concerns about possible hormonal effects.<sup>141</sup> However, while many chemicals are being banned, industrious chem-

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<sup>136</sup> See *id.* The study was conducted on 7,712 healthy Danish women in the Copenhagen City Heart Study. Researchers found a direct link among women exposed to high levels of Dieldrin to the development of breast carcinoma. Dieldrin was used on apples and other types of food crops up until the late 1970s. It was used for termite control until 1985. It was determined that more detailed analyses of Dieldrin levels in the United States, where blood levels are lower than in Denmark, should be performed to assess the risk involved. See *id.*

<sup>137</sup> See EPA Office of Prevention, Pesticides, and Toxic Substances, *Background on Endocrine Disruptors* (Sept. 24, 1997) <<http://www.epa.gov/scipoly/oscpendo/backgrnd.htm>>.

<sup>138</sup> See *id.*

<sup>139</sup> See *id.*

<sup>140</sup> See *id.* The endocrine system consists of a set of glands which produce hormones. These hormones are responsible for the development, growth, reproduction, and behavior of human and animal systems. Hormones are chemicals, produced by these glands, that travel through the bloodstream and are responsible for many biological responses in our body. Although hormones are necessary to sustain human life, an imbalance can cause negative effects on the immune system. For example, an excess of estrogen can exacerbate breast cancer, while a normal estrogen level begets a beneficial effect in women. See *id.*

<sup>141</sup> See EPA Office of Prevention, Pesticides, and Toxic Substances, *Questions & Answers, Potential of Chemicals to Affect the Endocrine System* (Mar. 1996) <<http://www.epa.gov/glnpo/toxteam/endoqa2.htm>>. An example of some chemicals already banned by the United States due to their known propensity to affect the endocrine system are PCBs and Organochlorine pesticides such as DDT, Chlordane, Aldrin/Dieldrin, Endrin, Kepone, Toxaphene, and others. See *id.*

ists are at work producing newer and more novel chemicals, with unknown effects on the delicate endocrine system.

Cancer from environmental hormones and pesticides is not the only health risk associated with such chemicals. Women are especially susceptible to estrogen-like activities initiated by such compounds.<sup>142</sup> Due to the abundance of estrogen from our environment, women may develop what is termed "estrogen dominance," a particularly difficult syndrome to treat.<sup>143</sup> Estrogen Dominance is associated with conditions such as sinus problems, headaches, dry eyes, asthma, and premenopause symptoms, as well as many others which may not yet have been causally related to the syndrome. Women in particular suffer many symptoms from the effects of Estrogen Dominance, such as pre-menstrual syndrome, swollen and tender breasts, weight gain, mood swings, and cramps.<sup>144</sup> Women struggling to juggle careers and families and who are exposed to high levels of stress are at a higher risk of illness as a result of estrogen overload.<sup>145</sup> Women caught in the cycle of stress and Estrogen Dominance are in a constant state of anxiety and tiredness at the same time.<sup>146</sup>

In his book, *What Your Doctor May Not Tell You About PreMenopause*,<sup>147</sup> Dr. John Lee clearly outlined the dangers of Estrogen Dominance to women who live in industrialized countries. He opined that xenohormones are a crucial factor accounting for much of the hormonal imbalance suffered by some women.<sup>148</sup> Xenohormones are fat-soluble and nonbiodegradable hormones which concentrate in hu-

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<sup>142</sup> See generally LEE & HOPKINS, *supra* note 5; see Sherrill Sellman, *Hormone Heresy, Estrogen's Deadly Truth, part 1*, NEXUS MAG., June-July 1996 (discussing the myths of the much-touted benefits of estrogen therapy, and outlining the dangers that estrogen therapy can pose to women).

<sup>143</sup> See LEE & HOPKINS, *supra* note 5, at 50. One reason Estrogen Dominance is difficult to treat is because it is not a commonly accepted illness by mainstream physicians. *See id.*

<sup>144</sup> See *id.* at 49. There are many other symptoms associated with Estrogen Dominance. It would be beyond the scope of this article to describe all of them.

<sup>145</sup> See *id.* at 50. A cycle occurs where stress may cause the Estrogen Dominance, which in turn may cause other symptoms, such as anxiety. The anxiety may affect a woman's adrenal glands, which are responsible for creating more Estrogen Dominance. *See id.*

<sup>146</sup> See *id.* Dr. Lee describes the cycle as "a constant state of wired but tired, which will eventually result in dysfunctional adrenal glands, blood sugar imbalances, and debilitating fatigue that may be diagnosed as chronic fatigue syndrome." *Id.*

<sup>147</sup> See *id.* at 48-51.

<sup>148</sup> See LEE & HOPKINS, *supra* note 5, at 82. According to Dr. Lee, xenohormones with estrogenic effects affect the body in several ways: "(a) some combine with estrogen receptor sites and activate estrogenic action; (b) some appear to induce formation of extra estrogen receptors; (c) others may inhibit the ability of the liver to excrete estrogen; and (d) some may occupy estrogen receptors and inhibit their action." *Id.*

man tissue.<sup>149</sup> Dr. Lee made the obvious point that continued exposure after birth naturally leads to higher xenohormone tissue concentrations, which in turn induces Estrogen Dominance and other irritating hormonal fluctuations.<sup>150</sup>

This article has attempted to illustrate that man-made pesticides and hormones are contaminating and infiltrating our natural existence. Our global economy has become dependent on technologically new synthetic chemicals. Data exposing the relationship of these chemicals to the disruption of our ecologically sound world would be a political disaster. But such data exists and must be addressed. The acclaimed book, *Our Stolen Future*,<sup>151</sup> presents mounting evidence of the havoc wreaked on our systems by environmental toxins.<sup>152</sup> Vice President Al Gore wrote a scintillating forward to the book, lauding it for reviewing the large and growing body of science linking synthetic chemicals to aberrant sexual development and behavioral and reproductive problems.<sup>153</sup> He advocated that the issues raised in *Our Stolen Future* were necessary and critical inquiries that must be dealt with.<sup>154</sup> Most compelling was Gore's position that the American people have a right to know the substances that they and their loved ones are being exposed to and the hazards associated with such substances.<sup>155</sup>

## V. AMERICANS TURN TO ORGANIC FOODS

Consumers were once lost in the sea of hormone- and chemical-laden food with nowhere to swim to safety. Among the hope to be delivered in the new millennium is an entire market of foods for the health conscious consumer. The new millennium will bring *choices*. The option to choose natural, chemical-free food is already becoming part of the everyday shopping experience.<sup>156</sup> Organic ranchers adver-

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<sup>149</sup> See *id.* at 86.

<sup>150</sup> See *id.*

<sup>151</sup> See generally COLBORN ET AL, *supra* note 61.

<sup>152</sup> See *id.*

<sup>153</sup> See *id.* at viii, ix. Vice President Al Gore states: "*Our Stolen Future* provides a vivid and readable account of emerging scientific research about how a wide range of manmade chemicals disrupt delicate hormone systems. These systems play a critical role in processes ranging from human sexual development to behavior, intelligence and the functioning of the immune system." *Id.*

<sup>154</sup> See *id.* at viii.

<sup>155</sup> See *id.* at ix.

<sup>156</sup> See *Now Appearing at a Store Near You: Organic Meat and Poultry*, ENVTL. NUTRITION, Mar. 1, 1999, available in 1999 WL 14372087.

tise their products on the Internet, offering consumers alternatives.<sup>157</sup> Therefore, consumers who are unable to obtain hormone- and chemical-free food at their local supermarket can tap into the technology of the Internet. Safe food is but a mouse click away.

Most consumers will not have to resort to the Internet to obtain their chemical-free beef. The U.S. Department of Agriculture has finally allowed the labeling of organic beef in addition to fruits, vegetables, and other organically grown foods.<sup>158</sup> Consumers will be able to cruise to the organic section of their supermarket and purchase organic meat and poultry products. The Organic Industry has advocated changing the USDA's meat labeling policy to allow for meat, poultry, and egg products to be sold with the "certified organic label."<sup>159</sup> The Food Safety and Inspection Service (FSIS) will provide guidance in the utilization of the claim "certified organic by a certifying entity."<sup>160</sup>

Organic products are rapidly gaining popularity, an obvious sign of America's frustration with toxic exposure. For example, Ellwood Thompson's Natural Market in Richmond, Virginia is hosting a series of classes featuring chefs from four local restaurants who will share tips on meal preparations with hormone-free meats and organic fruits and vegetables.<sup>161</sup> Similarly, some health-conscious restaurants now offer organic foods on their menu.<sup>162</sup> As stated, most major supermarket chains now carry organic foods.<sup>163</sup> This is in stark contrast to

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<sup>157</sup> See *Natural Beef—No Hormones, No Antibiotics, Natural Beef* (last modified Feb. 3, 2000) <<http://www.natural-beef.com>>. Painted Hills Natural Beef is only one example of producers of natural beef products. Painted Hills offers beef free of hormones and antibiotics.

<sup>158</sup> See *USDA to Allow Meat to be Labeled Organic*, *BUS. NEWS* (Jan. 15, 1999) <[http://www.foxmarketwire.com/wires/0114/f\\_ap\\_0114/f\\_ap\\_0114\\_63.sml](http://www.foxmarketwire.com/wires/0114/f_ap_0114/f_ap_0114_63.sml)>. Organic certification means that no pesticides or preservatives have been sprayed or added to growing fruits or vegetables. It also means that no chemicals or antibiotics are given to the organic animals. See *id.*

<sup>159</sup> See *Organic Labels Now Appearing on Food*, *HEALTH NEWS* (Feb. 1, 1999) <<http://herhealthonline.com/news/2-1-99/organic.html>>. Prior to this policy, certified organic meat products were the only category of certified organic products that were excluded from using the word "organic" on the label.

<sup>160</sup> "Certified Organic By" Labeling on Meat and Poultry Products, 64 *Fed. Reg.* 17,607, 17,607 (1999).

<sup>161</sup> See generally Jody Rathgeb, *Sparkling at 3 Area Restaurants*, *THE RICHMOND TIMES DISPATCH*, Mar. 25, 1999.

<sup>162</sup> See Bob Condor, *U.S. To Establish Rules On Organic Produce, Meats*, *CHI. TRIB.*, Dec. 16, 1997, available at <<http://www.chicago.tribune.com/tools/search/archives/form>> (discussing the evolution of the growing demand for organic foods).

<sup>163</sup> See *id.*

supermarket shelves ten years ago where anything organic was an anomaly.<sup>164</sup>

The newly approved organic market will provide more than chemical-free food. Consumers will be able to rely on the fact that foods they consume are unscathed by alien molecules. Americans may choose organic food only if the prices are similar to non-organic foods, but many may choose organic even if the food is pricier.<sup>165</sup> Americans have spoken; they are willing to pay the price for safety and they are finally getting the choice. But should consumers be made to pay a hefty price for safe food? The simpler solution would be to discontinue the use of hormones and chemicals in animals and plant products. Americans should not have to pay a beefy price for an unpolluted cut of beef.

CONCLUSION—THE FDA MUST REINSTATE DELANEY AND ADDRESS  
GENDER CONCERNS PRIOR TO APPROVAL OF HORMONES FOR  
LIVESTOCK

Chemical overload affects both sexes, but women are particularly susceptible to the hormonal and carcinogenic effect from many environmental stressors. Epidemiological studies show a strong correlation between populations eating hormone-laden meat and a high incidence of cancer.

Both men and women alike are told "eat your vegetables,"<sup>166</sup> but not "eat your pesticide residue-laden vegetables." The American Institute for Cancer Research has issued guidelines and recommendations on foods which might aid in cancer prevention, including a diet plentiful in fruits and vegetables.<sup>167</sup> But the Institute may not have taken into account the pesticides that would also be ingested. The American Cancer Society (ACS) estimates that about one-third of cancer deaths in the United States are due to dietary factors.<sup>168</sup> Many dietary factors such as high fat diets, alcohol consumption and intake of fruits and

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<sup>164</sup> See *id.* (stating that, "a decade ago, organic foods were a curiosity largely found in health-food stores and grocery co-ops. The movement, which harkens back to traditional farming practices, preaches that the miracle chemicals of American agriculture are bad for us. The counterculture ate up the message.").

<sup>165</sup> See *id.* Surveys indicate that about ninety percent of Americans will purchase organic foods if the prices are similar to non-organic foods. See *id.*

<sup>166</sup> See generally *PREVENTION: Fighting Cancer with Food*, HARV. HEALTH LETTER (Harv. Med. Sch. Health Publications Group, Cambridge, Mass.), Dec. 1997.

<sup>167</sup> See generally *id.*

<sup>168</sup> See generally *Eating to Avoid Cancer*, HARV. HEALTH LETTER (Harv. Med. Sch. Health Publications Group, Cambridge, Mass.), Mar. 1997.

vegetables have been associated with either an increase or decrease in cancer risk.<sup>169</sup> More attention should be paid to chemicals in our environment, and especially in the foods that are lauded as anti-cancer foods, such as fruits and vegetables. Scientific studies dating as far back as twenty-five years have shown a causal relationship between a high fat/protein diet and many diseases, including cancer.<sup>170</sup> In fact, in September 1996, the ACS released a recommendation that people should lower their meat consumption in order to decrease their risk of cancer.<sup>171</sup> Is meat with its high fat content the real culprit, or is it the FDA-approved growth hormones, the same hormones that have been rejected in Europe, that should bear the blame? Why is eating less meat associated with a lower incidence of many types of cancer?<sup>172</sup> Could it be chemical overload? American women are about five times more likely to develop breast cancer than are women in less developed countries.<sup>173</sup> In fact, when women from less developed countries adopt a Westernized diet and lifestyle, including meat laden with growth hormones and fruits and vegetables with pesticide residues, their cancer risks rise to the equivalent of women in the United States.<sup>174</sup>

The FDA, the EPA, and other governmental regulatory agencies must take a stand and embark on a toxic clean-up of our food supply. While the Europeans are erring on the side of caution, the United States is willing to err on the side of disaster. Until concrete scientific

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<sup>169</sup> See *id.*

<sup>170</sup> See generally *Nutrition-High Protein Diets: Where's the Beef?*, HARV. HEALTH LETTER, (Harv. Med. Sch. Health Publications Group, Cambridge, Mass.), Jan. 1, 1997 (discussing generally the health claims associated with high protein diets).

<sup>171</sup> See *id.* The ACS also recommended increasing the intake of plant foods.

<sup>172</sup> See generally *Risk Factors Diet Changes Can Reduce Cancer Risk*, CANCER WKLY. PLUS (C.W. Henderson, Atlanta, Ga.) Oct. 6, 1997 (stating that "[m]eat, at most, should be considered as a garnish . . . not the central part of the diet"). John Potter of the Cancer Prevention Research Program in Seattle, Washington, said that medical experts have long suspected the link between high intake of animal fats and meat and cancer development. See *id.* The article suggests that charred, cured, and smoked meats may be suspect. See *id.* This article does not address whether hormone or pesticide residues in meats have been studied to rule out a positive correlation. See *id.*

<sup>173</sup> See generally *Breast Cancer (Risk) Food Dyes May Raise Breast Cancer Risk*, Scientists Find, CANCER BIOTECHNOLOGY WKLY. (C.W. Henderson, Atlanta, Ga.) Nov. 13, 1995.

<sup>174</sup> See generally *id.* Craig Dees, head of the Molecular Toxicology Group in Oak Ridge National Laboratory (ORNL), suggests that Americans eat foods that contain levels of synthetic food dyes that are at least ten million times higher than the level of pesticides ingested. He states that "food dyes, pesticides such as DDT, and pollutants may be responsible for the increasing breast cancer rate among American women because they mimic the effects of the hormone estrogen."



studies are able to rule out the correlation between hormone-laden meats and certain pesticides in our foods, the epidemiological evidence demands that these toxins be removed from our food supply. Research must be directed at the association between toxic chemicals and the increase in cancer rates, rather than on personal risk factors such as heredity, childbearing, and menstrual history. It is easier to focus on the behavior of individual groups of women rather than on the overall exposure to estrogen-like carcinogens. Research should not focus on heredity or certain risk factors and ignore environmental factors.<sup>175</sup> If heredity were such a significant factor, why is it that women who come to the United States soon develop breast cancer at almost the same rate as American women?<sup>176</sup> Also, as discussed previously, girls who menstruate earlier, women who do not bear children until their later years, and those who use estrogen-based contraceptives are at a greater risk of developing cancer due to their high levels of reproductive hormones. But research has virtually ignored the role of estrogen-mimicking compounds found in meat treated with animal growth hormones or other chemicals capable of mimicking estrogenic compounds.<sup>177</sup>

There is an abundance of epidemiological evidence suggesting that carcinogenic chemicals/hormones promote breast cancer.<sup>178</sup> Although men are also at risk from exposure to environmental contaminants, women are uniquely affected, as evidenced by the statistics on deaths from breast cancer alone.<sup>179</sup> In addition, dietary habits which may affect both sexes also appear to be changing. For example,

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<sup>175</sup> A good example is that although women with a family history of breast cancer are more likely to develop breast cancer, no study has established whether that is a result of heredity or a shared toxic environment. *See generally Breast Cancer: The Poor Relation of Cancers; Includes Related Articles on Breast-Feeding, Mammography and Imperial Chemical Industries, INFORMED HOMEBIRTH-INFORMED BIRTH & PARENTING, SPECIAL DELIVERY*, Dec. 22, 1993.

<sup>176</sup> *See id.* (noting that "genetic vulnerability cannot explain the jump from one in twenty women getting cancer in their lifetime in 1950 to one in nine now").

<sup>177</sup> *See id.* Although an increase in dietary fat has been correlated with higher breast cancer rates, research has failed to establish whether the link is the fat or the toxins stored in the body fat of the animals that we eat.

<sup>178</sup> *See id.* Examples of such evidence are as follows: (1) the high rate of breast cancer in Long Island's Nassau and Suffolk counties, which were subjected to constant aerial spraying of DDT in the 1950s; (2) higher rates of breast cancer among female chemical factory workers who have been exposed to the chemical Dioxin; and (3) high rates of breast cancer among women golfers, who are exposed to larger than average amounts of pesticides due to their heavy usage of the golf courses. In addition, there is an EPA study indicating that those in counties with hazardous waste disposal sites are 6.5 times more likely to get breast cancer. These are but a few examples. *See id.*

<sup>179</sup> *See id.*

many more people are consuming an overabundance of meat as a result of the latest high-protein diet craze.<sup>180</sup> While the debate about the possible dangers inherent in high protein diets has focused on factors related to increased fat and protein, no studies have addressed the issue of the toxic hazards silently lurking in the slabs of meat. Testing hormone and chemical residues necessitates distinctive dimensions in a society enamored of the high protein, low carbohydrate diet. The perils of eating a high protein diet may not be the result of high protein intake, but may be attributed to residues in the protein. For consumers intent on eating meat and dairy products as a staple, they have incrementally increased the quantity of hormones and chemicals ingested. For these consumers, the aggregate effect of the residues may pose a greater hazard than the consumer eating a diet low in meat and dairy.

Regulatory agencies must consider gender risks as part of their research and development strategies. As stated previously, there is sufficient evidence pointing to the correlation between the intake of chemical- and hormone-laden foods and the fatalistic effects on the human reproductive system. Governmental agencies have a duty to hold manufacturers of these environmental toxins accountable if they deny consumers complete safety in favor of increased economic profit.

With respect to the growth hormones in our meat supply, Dr. Samuel Epstein<sup>181</sup> of the University of Illinois sums up the real issue rather simply: "the question we ought to be asking is not why Europe won't buy our hormone-treated meat, but why we allow beef from hormone-treated cattle to be sold to American and Canadian con-

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<sup>180</sup> See Martha Irvine, *High-Protein Diet Craze is Beefing Up Market Prices* (Oct. 22, 1999) (on file with author) ("The high-protein weight-loss diet has been promoted in such best sellers as 'Protein Power' and 'Dr. Atkins' New Diet Revolution.' It's a meat lover's dream because it recommends lots of protein instead of carbohydrates.").

<sup>181</sup> Samuel Epstein, M.D., is a Professor of Environmental and Occupational Medicine at the School of Public Health, University of Illinois Medical Center, Chicago. He has filed an affidavit in support of the EU ban. His affidavit reads in part:

[b]ased on a review of the scientific literature, Food and Drug Administration (FDA) Freedom of Information Summaries, other U.S. Government reports, and FAO/WHO reports, I conclude that the use of natural and synthetic anabolics in meat production poses serious carcinogenic and other hazards to consumers, with particular reference to breast and other reproductive cancers.

Aff. of Dr. Samuel Epstein in Support of the EU Ban on Trade in Hormone Treated Beef (on file with author).

sumers?"<sup>182</sup> Consumers expect the responsible U.S. agencies to provide a better answer than "Europe is wrong and we are right."

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<sup>182</sup> *Id.* Dr. Epstein, of the Cancer Prevention Coalition, released strong statements regarding hormone-treated meat:

[c]onfidential industry reports to the FDA, obtained under the Freedom of Information Act, reveal high residues of sex hormones in American beef; Following implants in cattle of Synoves-S, a combination of estradiol and progesterone, estradiol levels in meat increased up to 20-fold over what is considered normal. Based on conservative estimates, the amount of estradiol in two hamburgers eaten by an eight-year-old boy could increase his hormone levels by 10%; Much higher hormone levels are found in meat products following illegal implantation in cattle muscle tissue, which is commonplace in U.S. feed lots. *See id.* A random survey of 32 large feed lots found that as many as half of the cattle had visible "misplaced implants" in muscle, rather than under ear skin; Lifelong exposure to high residues of natural and synthetic sex hormones in meat products poses serious risks of breast and reproductive cancers, which have sharply increased in the U.S. since 1950. *See id.* Hormone residues are also suspected to be causal factors in premature sexual development in young girls; Repeated assurances on the safety of hormone-implanted meat by two World Health Organization bodies, the Food and Agriculture Organization (FAO) and the Codex Alimentarius Commission (Codex) reflect the biases of senior FDA and USDA officials and industry consultants, and rely heavily upon unpublished industry data and outdated scientific information.

*Id.*