# **Biotechnology and Consumer Decision-Making**

Joanna K. Sax\*

#### ABSTRACT

Society is facing major challenges in climate change, health care and overall quality of life. Scientific advances to address these areas continue to grow, with overwhelming evidence that the application of highly tested forms of biotechnology is safe and effective. Despite scientific consensus in these areas, consumers appear reluctant to support their use. Research that helps to understand consumer decision-making and the public's resistance to biotechnologies such as vaccines, fluoridated water programs and genetically engineered food, will provide great social value. This article is forward-thinking in that it suggests that important research in behavioral decision-making, specifically affect and ambiguity, can be used to help consumers make informed choices about major applications of biotechnology. This article highlights some of the most controversial examples: vaccinations, genetically engineered food, rbST treated dairy cows, fluoridated water, and embryonic stem cell research. In many of these areas, consumers perceive the risks as high, but the experts calculate the risks as low. Four major thematic approaches are proposed to create a roadmap for policymakers to consider for policy design and implementation in controversial areas of biotechnology. This article articulates future directions for studies that implement decision-making research to allow consumers to appropriately assign risk to their options and make informed decisions.

<sup>\*</sup> Visiting Faculty Member, James E. Rogers College of Law – University of Arizona (Fall 2016); Professor of Law, California Western School of Law; J.D., University of Pennsylvania Law School; Ph.D., University of Pennsylvania School of Medicine. The author acknowledges Professor Jane Bambauer and Professor Donald Smythe for detailed comments on a draft of this article. This article, or portions thereof, was presented to larger audiences at the Loyola University Chicago School of Law Faculty Speaker Series, the James E. Rogers College of Law – University of Arizona Faculty Enrichment Series, the Southern Methodist University Dedman School of Law Food Forum, the Texas A&M Law Review Symposium 2016, and the American Society of Law, Medicine & Ethics 2016 Health Law Professors Conference. The author wishes to thank all of the participants at these events for their helpful comments and input. The author also appreciates the helpful editing by the editors at the *Seton Hall Law Review*.

SETON HALL LAW REVIEW

[Vol. 47:433

INTRODUCTION
I. DECISION-MAKING THEORIES
A. Ambiguity 439
B. Affect
C. Ambiguity, Affect and Decision-Making
II. AREAS OF BIOTECHNOLOGY THAT FACE CONSUMER
OPPOSITION
A. Vaccines
B. GMOs
C. rbST
D. Fluoridated Water 457
E. Embryonic Stem Cell Research 459
III. CONSUMER DECISION-MAKING AND POLICY
A. Theme 1: Separate the Wheat from the Chaff: Allow
Consumers to make Informed Choices
B. Theme 2: Scientific Uncertainty is Different than
Risk
C. Theme 3: Explore Different Methods of
Communication that Consider the Role of Affect and
Ambiguity 478
D. Theme 4: Address the Difference between Values, Affect
and Ambiguity in Decision-Making
E. The Role of Risk-Perception in Policymaking
CONCLUSION

#### INTRODUCTION

Despite overwhelming scientific evidence supporting the application of biotechnology to address major social issues, consumers are resisting policies that apply science to solve major challenges. This article utilizes theories in behavioral decision-making research not only to articulate why consumers may be hesitant to accept biotechnology, but proposes to deeply study and analyze ways to assuage the public's concerns. Consumers are bombarded with conflicting information regarding each area of technology and, not surprisingly, struggle to separate the wheat from the chaff. А tremendous amount of resources is dedicated to evaluating risk, yet not enough attention is given to how consumers perceive risk. This lack of attention creates a major problem for policy implementation. In other words, expert analysis of risk is not translating into consumer perceptions of risk. This article seeks to present a roadmap of studies that implement decision-making research to translate the empirical evidence of risk analysis in ways that allow consumers to appropriately assign risk to various areas of biotechnology, such as vaccines.

Every day most of us experience the benefits of science and, in particular, biotechnology. Even the small parts of our days are influenced by biotechnology, such as pouring milk in our morning coffee, providing food for ourselves and our families, drinking water, and avoiding otherwise contractible diseases. These daily routines are enabled and facilitated by various scientific advances: rbST treated dairy cows, conventional and genetically engineered food, fluoridated water, and vaccines, respectively. Policies implementing these technologies, based on scientific evidence, provide great social value, even though consumers may not fully understand the underlying technology. Some consumers may not even think about the underlying technology, unless and until they are provided with information—or mis-information—that causes great concern.

Public health officials tout many of the advances in science as some of our greatest achievements, particularly fluoridated water and vaccination programs.<sup>1</sup> In general, public health officials promote group rights and look at the population as a whole when analyzing benefits. For example, if vaccination programs all but eliminate an otherwise serious disease, such as smallpox, with little to no otherwise

<sup>&</sup>lt;sup>1</sup> See, e.g., Community Water Fluoridation, CTR. FOR DISEASE CONTROL, http://www.cdc.gov/fluoridation/index.htm (last updated July 29, 2015); Why Are Childhood Vaccines So Important?, CTR. FOR DISEASE CONTROL, http://www.cdc.gov/vaccines/vac-gen/howvpd.htm#why (last updated May 19, 2014) [hereinafter CDC, Why Are Childhood Vaccines So Important?].

# SETON HALL LAW REVIEW [Vol. 47:433

measurable harm, then the benefit greatly outweighs the risk.<sup>2</sup> Increasingly, however, calls for the removal of rbST from dairy cows, elimination of fluoridated water, labeling of food based on safety concerns, and personal exemptions from vaccination programs are heard from consumers. It is important to understand not only why these consumers raise concerns (e.g., whether it is from marketing or political campaigns) but also, how to allay their concerns-especially if the concerns are based on inchoate fears. This tension between widespread policy implementation and opposition by individuals creates issues for innovation and policy implementation. This article attempts to articulate and understand consumer preference as it relates to the application of biotechnology. In the United States, the federal government invests the lion's share of resources in assessing risk, but there remains a pressing need for investment in understanding why consumers perceive risk differently than expert analysis.3

Given the strong scientific evidence supporting many of the widespread programs, such as vaccines and fluoridated water, we, as a society, need to understand why some consumers are resisting these programs, especially the mandatory programs.<sup>4</sup> Efforts are underway to remove fluoride from public water supplies, for example.<sup>5</sup> The discord with the application of biotechnology is not limited to widespread public health programs; it is also strong in other areas such as genetically engineered food, rbST treated cows, funding for embryonic stem cell research, and others. This article tackles these issues and articulates a theme that is seen throughout all of these controversial areas, which is that consumers are inappropriately assigning risk to the application of these scientific advances. To do this, this article builds on decision-making research to suggest reasons why consumers are averse to the implementation of policies that apply biotechnology.

In risk perception research, scholars study consumer preferences

<sup>&</sup>lt;sup>2</sup> See, e.g., Why Immunize?, CTR. FOR DISEASE CONTROL, http://www.cdc.gov/vaccines/vac-gen/why.htm (last updated Sept. 23, 2014) [hereinafter CDC, Why Immunize?].

<sup>&</sup>lt;sup>3</sup> *Cf.* WERNER TROESKEN, THE POX OF LIBERTY 1, 14–38 (2015).

<sup>&</sup>lt;sup>4</sup> See, e.g., George Johnson, The Widening World of Hand-Picked Truths, N.Y. TIMES, Aug. 24, 2015.

<sup>&</sup>lt;sup>°</sup> See Stephanie Innes, *Cavities Again? Blame the Tucson Water System*. . ., ARIZ. DAILY STAR, Nov. 2, 2014, http://tucson.com/news/science/health-med-fit/cavities-againblame-the-tucson-water-system/article\_33d26ed3-2fb0-5385-b14c-e97630237f4e.html ("An increasingly vocal opposition to fluoridated water has emerged in recent years, fueled by a distrust in government.").

for various technologies.<sup>6</sup> A profound example of a disconnect between scientists and consumers is the perception of risk of nuclear power.<sup>7</sup> While experts generally find nuclear power to be a safe and clean source of energy, consumers perceive it as a highly risky activity.<sup>8</sup> Understanding these perceptions of risk is a robust area of study and is important for both appreciating and assuaging public concerns and fears. Three Mile Island, the notorious nuclear power plant leak, is oft cited for qualifying the public push-back to nuclear power plants.<sup>9</sup> Empirical data, however, demonstrates that rates of cancer and other related diseases are no greater for the population surrounding Three Mile Island compared to the population in general.<sup>10</sup> In other words, there is no measurable health harm attributable to the leak. Despite this, research shows that consumers find nuclear power plants to be risky, with cost playing an additional role.<sup>11</sup> As such, the public perceptions and concerns have all but eliminated the nuclear power industry.<sup>12</sup> This has occurred despite expert opinion on safety and utility to the contrary.<sup>13</sup> Perhaps other energy industries have a vested interest in feeding consumer concerns; or perhaps the debate about

<sup>10</sup> *Id.* ("[C]omprehensive investigations and assessments by several well respected organizations, such as Columbia University and the University of Pittsburgh, have concluded that in spite of serious damage to the reactor, the actual release had negligible effects on the physical health of individuals or the environment.").

<sup>11</sup> See, e.g., Bryan Walsh, Nuclear Energy is Largely Safe. But Can it be Cheap?, TIME (July 8, 2013), http://science.time.com/2013/07/08/nuclear-energy-is-largely-safebut-can-it-be-cheap/ ("And while fears of accidents and radioactivity clearly play a role in that decline, cost is an even bigger factor.").

<sup>12</sup> See *id.* ("[I]n the U.S. and much of the rest of the developed world, nuclear energy is in retreat, with new reactors on hold and aging ones being retired. And while fears of accidents and radioactivity clearly play a role in that decline, cost is an even bigger factor.").

<sup>&</sup>lt;sup>6</sup> Paul Slovic, *Perception of Risk*, 236 SCI. 280, 281 (1987) [hereinafter Slovic, *Perception of Risk*]. The author thanks a colleague for introducing Paul Slovic's work to allow the author to understand and incorporate components of risk perception research into the author's research (personal communication).

<sup>&#</sup>x27; Id.

<sup>&</sup>lt;sup>8</sup> *Id.* (citing published articles therein).

<sup>&</sup>lt;sup>9</sup> See Backgrounder on the Three Mile Island Accident, U.S. NUCLEAR REG. COMMISSION, http://www.nrc.gov/reading-rm/doc-collections/fact-sheets/3mile-isle.html (last updated Dec. 12, 2014) ("A combination of personnel error, design deficiencies, and component failures caused the Three Mile Island accident, which permanently changed both the nuclear industry and the NRC. Public fear and distrust increased, NRC's regulations and oversight became broader and more robust, and management of the plants was scrutinized more carefully.").

<sup>&</sup>lt;sup>13</sup> See id. ("Accidents are rare, and those that have occurred—including the partial meltdown in Fukushima, Japan, in 2011—have resulted in few deaths. On a megawattper-megawatt basis, nuclear kills fewer people than almost any other source of electricity....").

# SETON HALL LAW REVIEW [Vol. 47:433

which source of energy is better—such as wind, solar, natural gas, or nuclear—makes it challenging for consumer decision-making, given the limitations of a typical consumer's knowledge about highly scientific information. In other words, the advantages and disadvantages of each type of energy source require complicated discussions that may require expertise.

A similar disconnect about the assignment of risk is occurring in the application of biotechnology. Sectors of the public are wary of various programs and technologies despite scientific consensus to the contrary. Understanding these perceptions is critical to creating policies that are acceptable to consumers—so that vaccinations programs, for example, do not face the same type consumer objections as nuclear power plants. Research is needed to get a foothold on understanding not only why consumer perceptions are different from expert analysis but to also evaluate approaches that allow consumers to appropriately assign risk.

This article addresses the important question of how to create policies that not only reap the benefits of biotechnology to solve major challenges, but also have the ability to be accepted and trusted by consumers. To begin this evaluation, Part I describes theories that elucidate how consumers appropriately or inappropriately assign risk as part of decision-making. This article draws on scholarship that advances two general theories—affect and ambiguity.<sup>14</sup> After this general explanation of decision-making theories, this article turns to a description of some major areas of biotechnology that are hotly debated. Part II thus describes the contours of debates surrounding vaccinations, genetically engineered food, rbST treated dairy cows, fluoridated water programs and embryonic stem cell research-this analysis includes both the scientific consensus and the various consumer perceptions. Finally, Part III combines the decision-making theories with the scientific areas to articulate four themes to be considered for creating policies that assuage public concerns and perceptions. These themes provide an overarching approach to understanding and addressing consumer concerns regarding the implementation of controversial areas of technology. The four themes are: (1) Separate the wheat from the chaff: allow consumers to make informed choices; (2) Scientific uncertainty is different than risk; (3) Explore different methods of communication that consider the role of affect and ambiguity; and (4) Address the difference between values,

438

<sup>&</sup>lt;sup>14</sup> Paul Slovic et al., *The Affect Heuristic*, 177 EUR. J. OF OPERATIONAL RES. 1333, 1333 (2007) [hereinafter Slovic, *The Affect Heuristic*]; Daniel Ellsberg, *Risk, Ambiguity, and the Savage Axioms*, 75 Q. J. OF ECON. 643, 643–69 (1961).

affect and ambiguity in decision-making. Within each theme, however, is a detailed discussion of the various similarities and differences between and among each example (vaccines, genetically engineered food, rbST, fluoridated water and embryonic stem cell research). Each example requires specific attention and proposals for conducting studies geared towards the individual issues raised, which are included herein. This article builds on many studies in the sciences, including decision-making research and the basic sciences, to promote future directions that acknowledge the problems we face and seeks to allow consumers to make informed decisions.

#### I. DECISION-MAKING THEORIES

How consumers assign risk to new technologies is a key component to understanding decision-making. Two major theories ambiguity and affect—help elucidate how consumers assign risk, especially when some information is unknown.

#### A. Ambiguity

Ambiguity is defined as "a quality depending on the amount, type, reliability and 'unanimity' of information, and giving rise to one's degree of 'confidence' in an estimate of relative likelihoods."<sup>15</sup> Daniel Ellsberg, the pioneer of the ambiguity theory, questioned the ability to predict a particular decision when uncertainty exists.<sup>16</sup> In his hypothetical experiment, Ellsberg presented subjects with two urns: the first urn contained a known mixture of colored balls (fifty percent red and fifty percent black) and the second urn contained an unknown mixture (although unknown to subjects, it actually contained the same percentage). Subjects would be paid \$100 if they selected a red ball and \$0 if they selected a black ball.<sup>17</sup> When asked which urn they wished to choose from, subjects preferred choosing from urn one (with the known ratio).<sup>18</sup> That is, subjects preferred to bet on the urn with the known risk rather than the second urn, which contained an unknown risk.<sup>19</sup> Put differently, subjects tend to prefer to bet on a known probability rather than an unknown probability.<sup>20</sup> This phenomenon, where subjects are more likely to choose a known risk

<sup>&</sup>lt;sup>15</sup> Ellsberg, *supra* note 14, at 657.

 $I_{17}^{16}$  Id. at 656.

 $I_{17}^{17}$  Id. at 650.

<sup>&</sup>lt;sup>18</sup> *Id.* at 657.

<sup>&</sup>lt;sup>19</sup> Id. at 657–58; see also Laura L. Blaisdell et al., Unknown Risks: Parental Hesitation about Vaccination, 36 MED. DECISION MAKING 479, 480 (2016).

<sup>&</sup>lt;sup>o</sup> Blaisdell, *supra* note 19.

SETON HALL LAW REVIEW [Vol. 47:433]

compared to an unknown risk underscores the theory of ambiguity in decision-making.<sup>21</sup> Numerous studies have tested this directly or indirectly.<sup>22</sup> As discussed in greater detail in Part II, this is particularly relevant to how consumers perceive risk with new technology, especially when all the risks are unknown.

Research supporting ambiguity in decision-making also focuses on how subjects make decisions when uncertainty for the possible outcome is not known.<sup>23</sup> In other words, if a person is unsure of a particular outcome, the state of potential probabilities is ambiguous.<sup>24</sup> Studies have shown that people are averse to ambiguity—which means that if the probability of a risk is presented in an ambiguous way, subjects tend to be averse to toward the ambiguity.<sup>25</sup> For example, "[w]hen ambiguity about vaccination risk was caused by salient missing information about the risks from vaccination-a child had a high risk of being harmed by the vaccine, or no risk at all, but it was impossible to find out which-subjects were more reluctant to vaccinate."26 Subjects demonstrate aversion to ambiguous information-especially when they perceive that they cannot assign a risk to a particular outcome. In other words, consumers may inappropriately assign risk when presented with ambiguous information. Examples of ambiguity aversion are discussed in Part II.

B. Affect

Affect is defined as "the specific quality of 'goodness' or 'badness' (a) experienced as a feeling state (with our without consciousness) and (b) demarcating a positive or negative quality of a stimulus."<sup>27</sup> In other words, affect refers to the reliance on a feeling to guide decision-making.<sup>28</sup> That is, the "faint whisper of emotion" guides decision-making; "[p]leasant feelings motivate actions that people will anticipate will reproduce those feelings [and] [u]npleasant feelings

See id.

<sup>&</sup>lt;sup>21</sup> *Id.* 

<sup>&</sup>lt;sup>22</sup> See, e.g., *id.*; Joanna K. Sax & Neal Doran, Food Labeling and Consumer Association with Health, Safety and Environment, 44 J. L. MED. & ETHICS 630, 635–37 (2016) [hereinafter Sax & Doran]; Colin Camerer & Martin Weber, Recent Developments in Modeling Preferences: Uncertainty and Ambiguity, 5 J. OF RISK AND UNCERTAINTY 325, 333– 41 (1992) (describing empirical studies of ambiguity).

<sup>&</sup>lt;sup>23</sup> See Camerer & Weber, supra note 22, at 325.

<sup>&</sup>lt;sup>24</sup> See id. at 331 ("When a person is not sure what the distribution of probabilities is, we call the state probabilities *ambiguous.*").

 $<sup>\</sup>frac{25}{26}$  See id. at 354.

<sup>&</sup>lt;sup>20</sup> *Id.* <sup>27</sup> D

<sup>&</sup>lt;sup>27</sup> Paul Slovic & Ellen Peters, *Risk Perception and Affect*, 15 CURRENT DIRECTIONS IN PSYCHOL. SCI. 322, 322 (2006) [hereinafter Slovic, *Risk Perception and Affect*].

motivate actions that people will anticipate will avoid those feelings."<sup>29</sup> Important research by Paul Slovic and others shows that affect impacts how subjects correlate perceptions of risks with benefits.<sup>30</sup> That is, subjects perceive activities that have high benefits as low risk and vice versa. By way of example, in a study conducted by Alhakami and Slovic, subjects demonstrated this inverse relationship with pesticide use-, i.e., high risk and low benefit.<sup>31</sup> These results were linked to how subjects viewed the goodness or badness of the activity and assigned risk accordingly.<sup>32</sup> According to Slovic and Peters, this finding demonstrates that "[i]f their feelings toward an activity are favorable, they tend to judge the risks as low and the benefits as high; if their feelings toward the activity are unfavorable, they tend to make the opposite judgment-high risk and low benefit (i.e., the affect heuristic)."<sup>33</sup> Referring back to the difference of risk perceptions regarding nuclear energy (which was discussed in the introduction), Slovic and colleagues suggest that affect underscores the reasons why the feeling of dread leads people to assign a high risk to exposure to radiation from nuclear power plants as compared to exposure to radiation from x-rays.<sup>34</sup> As noted by Slovic and Peters, "an assessment not shared by risk experts."35

In decision-making, consumers may not always maximize expected utility; rather, they may ask themselves how they feel about a particular decision.<sup>36</sup> Or, if consumers are experiencing a particular feeling at a given time, this emotional state will impact their decision processes.<sup>37</sup> For example, emotional states such as anger and arousal

<sup>&</sup>lt;sup>29</sup> Id.

<sup>&</sup>lt;sup>30</sup> See id. at 323; Slovic, The Affect Heuristic, supra note 14, at 1333–34.

<sup>&</sup>lt;sup>31</sup> Slovic, *Risk Perception and Affect, supra* note 27, at 323 (referring to study conducted by Alhakami and Slovic).

<sup>&</sup>lt;sup>32</sup> Id.

<sup>&</sup>lt;sup>33</sup> *Id.* (internal citation omitted).

<sup>&</sup>lt;sup>34</sup> Id.

<sup>&</sup>lt;sup>35</sup> Id.

<sup>&</sup>lt;sup>36</sup> See Paul Slovic, What's Fear Got to Do with It? It's Affect we Need to Worry About, 69 Mo. L. REV. 971, 973 (2004) [hereinafter Slovic, What's Fear Got to Do with It?] ("As life became more complex and humans gained more control over their environment, analytic tools were invented to 'boost' the rationality of our experiential thinking. Subsequently, analytic thinking was placed on a pedestal and portrayed as the epitome of rationality. Affect and emotion were seen as interfering with reason."); Ellen Peters et al., Affect and Decision Making: A "Hot" Topic, 19 J. BEHAV. DECISION MAKING 79, 80 (2006) ("First, affect can act as information: at the moment of judgment or choice, decision makers consult their feelings about a choice and ask, 'How do I feel about this?").

Peters et al., *supra* note 36, at 81–83.

SETON HALL LAW REVIEW [Vol. 47:433]

impact how subjects make decisions.<sup>38</sup> Importantly, feelings come on quickly—and this surge can impact decision-making at a particular point in time.<sup>39</sup> These feelings impact risk assessment.<sup>40</sup>

Survival requires that humans assess risk from different situations and then either avoid risky situations or design around them.<sup>41</sup> In the contemporary times, consumers are assessing risk as they are exposed to various technologies; but given the complicated nature of technology, it can be challenging for a typical consumer to fully evaluate and assign risk to a new technology. "The dominant perception for most Americans (and one that contrasts sharply with the views of professional risk assessors) is that they face more risk today than in the past and that future risks will be even greater than todav's."42 Understanding how consumers assign risk-and what underlies this decision-making process—is important for implementing and regulating policies that relate to health and safety.<sup>43</sup>

#### C. Ambiguity, Affect and Decision-Making

Decision-making is a complicated process. Although it cannot be neatly condensed into these two theories—ambiguity and affect—they can be (and have been) empirically tested and used to assist with understanding consumer perceptions of technology.<sup>44</sup> Both of these theories can operate at the same time, especially because they both apply to perceptions of risk. In the case of biotechnology, unknown risks exist and so we need to understand how consumers perceive and weigh those risks.

In the Internet age, consumers can Google anything and a wide variety of information will be presented. If, for example, a consumer

 $<sup>^{38}</sup>_{39}$  *Id.* at 81.

<sup>&</sup>lt;sup>39</sup> See Slovic, What's Fear Got to Do with It?, supra note 36, at 971.

<sup>&</sup>lt;sup>40</sup> See id. at 976 ("Evidence of risk as feelings was present (though not fully appreciated) in early psychometric studies of risk perception. Those studies showed that feelings of dread were the major determiner of public perception and acceptance of risk for a wide range of hazards.").

<sup>&</sup>lt;sup>41</sup> See Slovic, Perception of Risk, supra note 6, at 280.

 $<sup>^{42}</sup>$  Id.

<sup>&</sup>lt;sup>43</sup> *Id.* ("The basic assumption underlying these efforts is that those who promote and regulate health and safety need to understand the ways in which people think about and respond to risk.").

<sup>&</sup>lt;sup>44</sup> This article does not suggest that other theories and approaches are not also involved, but instead advocates that the role of affect and ambiguity are understudied in this area. For other approaches, see, for example, John Bohannon, *Government Nudges' Prove their Worth*, 352 SCI. 1042, 1042 (2016), for a discussion of successful government nudges; see also Dan M. Kahan, *A Risky Science Communication Environment for Vaccines*, 342 SCI. 53, 53–54 (2013), for a discussion addressing the role of cultural cognition in risk assessment.

searches for information regarding vaccinations and autism, websites will pop up that promote this linkage. Despite the scientific consensus that vaccinations do not cause autism, the public perception still exists. When parents are making a decision as to whether to vaccinate their child or not, they are weighing risks. Consumers may, for example, have difficulty assigning risk to vaccinations if they perceive there are unknowns (ambiguity) or that vaccinations may hurt their children (affect). Consumers may be subject not only to conflicting information, but may also have trouble evaluating whether the source is credible. If one medical professional touts a linkage between vaccines and autism, then how do consumers weigh information from other medical professionals that no linkage exists?

The next section turns to examples in biotechnology where consumers may have difficulty assigning risk either because the information is unknown or because information impacts the feelings they experience as they make a decision.

# II. AREAS OF BIOTECHNOLOGY THAT FACE CONSUMER OPPOSITION

This section addresses some controversial examples of biotechnology wherein public calls for regulation or elimination are not in accord with the scientific consensus. The underlying science of each area is described in order to guide the discussion regarding what risks are known and unknown. This section will also highlight where the controversy about each topic exists.

#### A. Vaccines

The development of vaccines to eradicate disease is considered a medical breakthrough.<sup>45</sup> Smallpox, polio, measles, mumps, rubella, and other diseases that crippled and killed people can now be avoided through the use of vaccines.<sup>46</sup> Vaccines are widely supported by public health officials as a main mechanism to avoid the spread of disease.<sup>47</sup> Vaccines are regarded as safe and effective.<sup>48</sup>

<sup>&</sup>lt;sup>45</sup> See Achievements in Public Health, 1900–1999 Impact of Vaccines Universally Recommended for Children—United States, 1990–1998, 48 MORBIDITY & MORTALITY WKLY. REP. 243, 243–48 (1999), https://www.cdc.gov/mmwr/preview/mmwrhtml/000568 03.htm ("Vaccines are one of the greatest achievements of biomedical science and public health.").

<sup>&</sup>lt;sup>40</sup> See CDC, Why are Childhood Vaccines So Important?, supra note 1.

<sup>&</sup>lt;sup>47</sup> See CDC, Why Immunize?, supra note 2.

<sup>&</sup>lt;sup>48</sup> Vaccine Safety, CTR. FOR DISEASE CONTROL, http://www.cdc.gov/vaccinesafety/ index.html (last updated Nov. 2, 2015) [hereinafter CDC, Vaccine Safety] ("Data show that the current U.S. vaccine supply is the safest in history.").

## SETON HALL LAW REVIEW [Vol. 47:433

Vaccines are small doses of a dead or attenuated (not able to reproduce) virus. Upon administration of a vaccine, the body's immune system generates an immune response by creating antibodies to kill the virus.<sup>49</sup> In the case of vaccines, the injected virus is either dead or attenuated, so the disease can never manifest but the immune reaction is activated nevertheless.<sup>50</sup> Once the antibodies are created the immune system now has a memory bank, which can be analogized to a filing system, as to how to fight that particular virus.<sup>51</sup> This is why the term "immunized" is used. Now, if the body ever encounters the actual virus through real contact, the immune system can return to its files, quickly call up the particular antibody, and efficiently fight off the virus before the virus can infiltrate and replicate in the body.<sup>52</sup> Put differently, vaccines teach the body how to defend against particular diseases, if exposed.

Vaccines are not without any risk. Patients can have allergic reactions or infection at the site of injection. A National Vaccine Injury Compensation Program, established by the US government, compensates patients who are injured as a result of vaccines.<sup>53</sup> In balancing the risk to benefit ratio, the overwhelming response by physicians and public health officials is to support vaccine regiments.

About twenty years ago, a research team published a report in the *Lancet* identifying a connection between vaccines and autism.<sup>54</sup> This research paper—which later had to be retracted because the data did not support the conclusion—still managed to instigate an enormous anti-vaccination campaign. Individuals claimed that the mandatory

444

<sup>&</sup>lt;sup>49</sup> See Understanding How Vaccines Work, CTR. FOR DISEASE CONTROL, http://www.cdc.gov/vaccines/hcp/conversations/downloads/vacsafe-understandcolor-office.pdf (last visited May 24, 2016) ("Vaccines help develop immunity by imitating an infection. This type of infection, however, does not cause illness, but it does cause the immune system to produce T-lymphocytes and antibodies.... Once the imitation infection goes away, the body is left with a supply of 'memory' Tlymphocytes, as well as B-lymphocytes that will remember how to fight that disease in the future.").

<sup>&</sup>lt;sup>50</sup> *See, e.g., id.* (describing live, attenuated viruses and inactivated viruses).

<sup>&</sup>lt;sup>51</sup> See, e.g., *id.* (describing the five main types of vaccines commonly administered).

<sup>&</sup>lt;sup>52</sup> *Id.* ("Once the imitation infection goes away, the body is left with a supply of 'memory' T-lymphocytes, as well as B-lymphocytes that will remember how to fight that disease in the future.").

<sup>&</sup>lt;sup>55</sup> See National Vaccine Injury Compensation Program, HEALTH RES. & SERVS. ADMIN., http://www.hrsa.gov/vaccinecompensation/ (last updated Feb. 2016).

<sup>&</sup>lt;sup>54</sup> A.J. Wakefield et al., *Ileal-Lymphoid-Docular Hyperplasia, Non-Specific Colitis, and Pervasive Developmental Disorder in Children,* 351 THE LANCET 637, 637–41 (1998), http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(97)11096-0.pdf. It is critical to note, however, that this misleading publication was subsequently retracted.

vaccination programs violated parental autonomy—especially given the concerns about the link between vaccines and autism. Despite the retraction of the *Lancet* paper and many dozens of studies demonstrating that vaccines are not linked to autism, this view that vaccines cause autism persists. An Internet search for "vaccines and autism" provides results that can tell a parent anything that s/he wants to believe, regardless if it is based on scientific evidence. Put differently, despite scientific evidence that vaccines are not linked to autism, consumers may still read information on the Internet that says otherwise.<sup>55</sup>

Both individual and religious objections to vaccines led to the passage of state laws exempting children from mandatory vaccination requirements. Most notably, California was at the forefront of the individual exemptions. Over time, more and more children stopped receiving vaccines. In 2014, a major measles outbreak at Disneyland in southern California called attention to the dangerous realities that can occur when people stop being vaccinated.<sup>56</sup> Public health officials believe that due to vaccination exemptions, an outbreak occurred. This is particularly troubling for parents who cannot vaccinate their children for medical reasons and rely on the requisite level of herd immunity.<sup>57</sup> In response to this outbreak, on June 30, 2015, California Governor Jerry Brown signed SB277, which removed the individual exemptions for children, leaving only a medical exemption.<sup>58</sup>

Laura Blaisdell and colleagues conducted an insightful study by interviewing focus groups to understand why parents might be hesitant or reject vaccinating their children.<sup>59</sup> A number of themes were

<sup>&</sup>lt;sup>55</sup> See, e.g., Whet Moser, Why Do Affluent, Well Educated People Refuse Vaccines?, CHICAGO (Mar. 26, 2014), http://www.chicagomag.com/city-life/March-2014/Why-Is-Vaccine-Refusal-More-Prevalent-Among-the-Affluent/ ("Social networks (actual ones) seem to be incredibly important in forming opposition to vaccines, either in whole or in part: 'in this study, parents who didn't follow CDC guidelines were more likely to have extensive "source networks" that included books, blogs, websites, and magazine articles to which they turned for vaccine-related information.").

<sup>&</sup>lt;sup>56</sup> *Measles*, CAL. DEP'T OF PUB. HEALTH, https://www.cdph.ca.gov/HEALTHINFO /DISCOND/Pages/Measles.aspx (last updated Feb. 2, 2016).

<sup>&</sup>lt;sup>57</sup> See, e.g., NICOLE HUBERFELD, ELIZABETH WEEKS & KEVIN OUTTERSON, THE LAW OF AMERICAN HEALTH CARE 1, 12–13 (2016).

<sup>&</sup>lt;sup>58</sup> See Letter from Jerry Brown, Governor, State of Cal., to Members of Cal. State Senate (June 30, 2015), https://www.gov.ca.gov/docs/SB\_277\_Signing\_Message.pdf; see also Editorial, California Settles the Vaccination Question, L.A. TIMES (June 30, 2015, 2:43 PM), http://www.latimes.com/opinion/editorials/la-ed-vaccination-bill-signedinto-law-in-california-20150701-story.html ("With Gov. Jerry Brown's swift signature Tuesday on a tough new mandatory vaccination bill, the state has established itself as a national leader on public health.").

Blaisdell, supra note 19, at 479-80.

## SETON HALL LAW REVIEW [Vol. 47:433

confirmed and elucidated among Vaccine Hesitant Parents (VHPs).<sup>60</sup> First, VHPs expressed that the risks associated with vaccinations or nonvaccinations are unknown, and that the long-term risks associated with vaccinations are similarly unidentified, including for example, linkage to ailments and diseases.<sup>61</sup> Blaisdell and colleagues learned that VHPs who perceived vaccinations as risky stated that they were fearful of additives, the permanency of the decision, and that their infants were too young to process the vaccination.<sup>62</sup> These parents also perceived the risk of contracting a vaccine-preventable disease as low, and based their perception on low-risk environments, low-severity of disease, and healthy environments.<sup>63</sup> When pressed about what the parents would do if their child was exposed to a vaccine-preventable disease, they responded that they would promptly be able to detect, obtain treatment, or even treat the disease themselves.<sup>64</sup> In some cases, they expressed that the symptoms and treatment of diseases were known qualities, which suggested they could assign a risk to known attributes.<sup>bb</sup>

Within the VHP focus groups, some decided to either delay vaccination, change the vaccination schedule, or refuse vaccination altogether, thus a spectrum of perceived risks was found.<sup>66</sup> The quotes from the VHP participants are particularly illustrative of how VHPs perceive risk, especially when there are unknowns; a sampling of which is reproduced here:<sup>67</sup>

- "We don't know the long term side effects of some of these things. A doctor can't tell me 'Oh there's no long-term side effects'... because [they] don't know. It stays in your body forever, and there's all sorts of things going on that we can't attribute to any particular thing. Who's to say it's not [vaccination], because we can't see the link?"
- "One of the scary things about vaccines is that once it's done, it's done. You can't undo it. So you know I have this kid and maybe or maybe not vaccines have an effect on his progression in his life at this point."

<sup>66</sup> See id. at 485-87.

<sup>&</sup>lt;sup>60</sup> *Id.* at 480, 485–87.

<sup>&</sup>lt;sup>61</sup> *Id.* at 481–83.

<sup>&</sup>lt;sup>62</sup> Id.

<sup>&</sup>lt;sup>63</sup> *Id.* at 483–84.

<sup>&</sup>lt;sup>64</sup> *Id.* at 484.

<sup>&</sup>lt;sup>b5</sup> Blaisdell, *supra* note 19, at 484 ("I think that now if you can catch something, all these dreadful diseases, if you rush to the hospital right away they can probably save your life. So I'd rather go with that and see if something happens and then go that way [vaccinate].").

Id. at 483–85.

- "We don't send them to any daycares. I felt like they weren't exposed to a lot of different kids all day long, or for long periods of time without me around watching them and keeping them safe. It doesn't mean they are not gonna get a disease, it also means that they have a less chance."
- "I think that now if you catch something, all these dreadful diseases, if you rush to the hospital right away they can probably save your life. So I'd rather go with that and see if something happens then go that way [vaccinate]."<sup>68</sup>

Blaisdell and colleagues utilized the ambiguity decision-making theory not only to categorize the reasoning of the VHPs, but also suggest that understanding how VHPs assign risk can be used to educate and address individual concerns.<sup>69</sup>

Interestingly, the largest group of anti-vaccine advocates turns out to be upper-middle class white women.<sup>70</sup> It is unclear why this group, specifically, questions the validity and safety of vaccines, but some hypothesize that they are merely less trusting of medical authorities generally.<sup>71</sup> Another reason could be the luxury of wanting to return to a more wholesome state when things were simpler—we see this with food choices, homeopathic treatments, and avoiding the "poisons" in vaccinations.<sup>72</sup>

While the Blaisdell study nicely categorizes the responses by VHPs into risk perceptions based on ambiguity, many of the responses suggest affect could play a role in risk perception. If VHPs perceive that a vaccine will harm their child, they will feel "badness" about making a decision to vaccinate. Or, conversely, a VHP may experience "goodness" of refusing a vaccine because s/he perceives they have averted a high-risk situation. This scenario nicely fits into Slovic and colleagues' theory that when a subject views the risk as high, they also view the benefit as low.<sup>73</sup>

<sup>&</sup>lt;sup>68</sup> Id.

 $<sup>^{69}</sup>$  *Id.* at 479–80.

 $<sup>^{70}</sup>_{71}$  Id.

<sup>&</sup>lt;sup>11</sup> Moser, *supra* note 55 ("Parents whose children have been exempted from vaccinations have, unsurprisingly, less trust in a long list of authorities, from health care professionals to the CDC.").

<sup>&</sup>lt;sup>72</sup> See, e.g., Rachel Dunlop, 9 Vaccination Myths Busted. With Science!, MAMAMIA (Nov. 12, 2011), http://www.mamamia.com.au/vaccination-myths-busted-by-science-cheat-sheet-on-immunisation/ (discussing vaccination myths); see also Renee Shaw Hughner et al., Who are Organic Food Consumers? A Compilation and Review of Why People Purchase Organic Food, 6 J. CONSUMER BEHAV. 94, 101–03 (2007).

Slovic, Risk Perception and Affect, supra note 27, at 323 (see citation therein).

## SETON HALL LAW REVIEW [Vol. 47:433]

If the VHPs existed in a vacuum, the discussion might simply turn to a debate about whether parents are harming their children by refusing to vaccinate. But, the problem with allowing individuals to opt-out of vaccinating their children is that it has a ripple effect. To be effective in group settings, such as school classrooms, the compliance rate with vaccinations needs to be at a level to achieve the requisite herd immunity. California, for example, now requires that children attending preschool and public school be vaccinated absent a medical contraindication.<sup>74</sup> It is possible that consumers also have an affective response to the term "mandatory."

An important policy issue is how to educate the VHPs so that they can appropriately assign risk and make an informed decision. Simply providing VHPs with the scientific consensus is probably not enough; otherwise, we would likely not see this problem manifesting, especially among college-educated women. Another policy concern is differentiating for VHPs the existing knowledge about vaccines as compared to other areas whether medical professionals have had to backtrack, such as with nutritional recommendations. Part III explores various options to address this issue.

#### B. GMOs

Genetically Modified Organisms (GMOs) are the subject of major public debate.<sup>75</sup> Although the term genetically engineered (GE) food is a better term to describe this sector of the food supply, this article will use the colloquial term GMO. GMOs, collectively, are foods that have been altered through the application of biotechnology. GMOs are a more precise application of genetic engineering compared to conventional breeding.

Our entire food supply is genetically modified.<sup>76</sup> Conventional breeding utilizes several techniques to obtain desired characteristics.<sup>77</sup>

<sup>&</sup>lt;sup>74</sup> S.B. 277, 2015–16 Reg. Sess. (Cal. 2015); *see also* Tara Haelle, *California Vaccination Bill SB 277 Signed By Governor, Becomes Law*, FORBES (June 30, 2015, 2:14 PM), http://www.forbes.com/sites/tarahaelle/2015/06/30/california-vaccination-bill-sb-277-signed-by-governor-becomes-law/#6091044a1233.

<sup>&</sup>lt;sup>75</sup> William Saletan, Unhealthy Fixation: The War Against Genetically Modified Organisms is Full of Fearmongering, Errors, and Fraud. Labeling Them Will Not Make You Safer, SLATE (July 15, 2015, 5:45 AM), http://www.slate.com/articles/health\_and \_science/science/2015/07/are\_gmos\_safe\_yes\_the\_case\_against\_them\_is\_full\_of\_fra ud\_lies\_and\_errors.html.

<sup>&</sup>lt;sup>6</sup> Sax & Doran, *supra* note 22, at 630; *cf.* Saletan, *supra* note 75.

<sup>&</sup>lt;sup>77</sup> R. Panda et al., *Challenges in Testing Genetically Modified Crops for Potential Increases in Endogenous Allergen Expression for Safety*, 68 ALLERGY: EUR. J. ALLERGY & CLINICAL IMMUNOLOGY 142, 142 (2013), http://onlinelibrary.wiley.com/doi/10.1111/all.12076 /pdf.

Conventional tactics such as selective breeding, x-rays, and chemical mutagenesis are employed to create and select for an "improved" domestic crop or animal.<sup>78</sup> The genetic modifications using conventional methods, along with seed selection by commercial breeders, have proved—over hundreds of years—to be safe, and food created through conventional methods easily enters the marketplace.<sup>79</sup>

Despite misperceptions of some of the public, organic food is also genetically modified, but through conventional methods.<sup>80</sup> Organic farmers are growing domesticated crops selected for desired traits. The term "organic" does not refer to whether the crop has genetic advantages through selective breeding.<sup>81</sup> Put differently, we are not eating wild-type varieties; we are eating domesticated crops that are genetically modified.

The technology to create food from GMOs is a precise mechanism to accomplish what we already do in our food supply.<sup>82</sup> Unlike conventional breeding techniques, genetic engineering techniques allow for a precise modification to obtain a desired trait. In conventional breeding techniques, to obtain a desired trait, the seed may also carry hundreds to thousands of other mutations—most of which are never characterized.<sup>83</sup> In other words, genetic engineering

<sup>79</sup> See id. at 494 ("Nevertheless, such 'non-recombinant DNA transgenic varieties' (as they might be called) have been introduced safely into commercial cultivation around the world for more than a half-century without the need for premarket regulatory approvals.").

<sup>&</sup>lt;sup>78</sup> See, e.g., Gregory Conko et al., A Risk-Based Approach to the Regulation of Genetically Engineered Organisms, 34 NATURE BIOTECHNOLOGY 493, 494 (2016) (internal citations omitted) ("When plant breeders have exhausted the genetic resources (germ, plasm) within their crop's species, they have employed several techniques, such as mutagenesis and wide-cross hybridization, to introduce new genes or alleles into their cultivars. By the middle of the past century, X-ray and other mutagens were being used routinely and at scale to obtain a range of genetic changes, from point mutations to translocations in interspecific hybrids; the latter allowed pieces of chromosomes from wild species to integrate or translocate onto crop chromosomes. Mutation breeding is now routinely accomplished with other sources of ionizing radiation and with mutagenic chemicals.").

<sup>&</sup>lt;sup>80</sup> See, e.g., David Newland, Sorry Hipsters, That Organic Kale is a Genetically Modified Food, SMITHSONIAN.COM (Sept. 10, 2014), http://www.smithsonianmag.com/science/sorry-hipsters-organic-kale-genetically-modified-food-180952656/?no-ist.

<sup>&</sup>lt;sup>81</sup> See generally Organic Agriculture, U.S. DEP'T OF AGRIC., http://www.usda.gov/wps/portal/usda/usdahome?contentidonly=true&contentid=o rganic-agriculture.html (last updated Jan. 9, 2015) (describing organic agriculture).

<sup>&</sup>lt;sup>82</sup> Steven H. Strauss & Joanna K. Sax, *Ending Event-Based Regulation of GMO Crops*, 34 NATURE BIOTECHNOLOGY 474, 476 (2016) [hereinafter Strauss & Sax].

<sup>&</sup>lt;sup>83</sup> See Conko et al., *supra* note 78, at 494 (internal citation omitted) ("Many crops contain genes crossed in from wild relatives that have no history of safe use and that may even be known to produce toxins or allergens. In wide-cross hybridization, the genes or alleles of interest are moved into the crop—along with countless other

SETON HALL LAW REVIEW [Vol. 47:433

technology allows scientists to obtain desired traits with less genetic mutations.<sup>84</sup>

In the 1980s, the Food and Drug Administration (FDA) expressed concerns about increased expression levels of endogenous toxins or allergens that may result from genetic engineering techniques.<sup>85</sup> This is because changes to the genetic profile can increase or decrease the expression of other genes.<sup>86</sup> Since then, many dozens of studies have demonstrated that technology used to create GMO crops does not lead to the mass destabilization of genome expression that the FDA was worried about.<sup>87</sup>

Many decades of research demonstrate that plant genomes are highly unstable, with many epigenetic events occurring over time.<sup>88</sup> Gene expression profiles cannot be captured at any one time, given the widespread changes.<sup>89</sup> Transpositions are often occurring, which will shake up the genetic sequence.<sup>90</sup> Due to the high plasticity of plant

<sup>86</sup> *Id.* ("DNA segments introduced using the new techniques insert semi-randomly into the chromosome, frequently in tandem multiple copies, and sometimes in more than one site on the chromosome. Both the number of copies of the gene and its location in the chromosome can affect its level of expression, as well as the expression of other genes in the plant.").

450

genetic changes of unknown function, including those that potentially could alter the weediness of the plants or the allergenicity, toxicity or nutritional value of foods derived from them.").

<sup>&</sup>lt;sup>84</sup> Cf. Strauss & Sax, *supra* note 82, at 475.

<sup>&</sup>lt;sup>85</sup> Statement of Policy – Food Derived from New Plant Varieties, Guidance to Industry for Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984 (May 29, 1992),

http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInf ormation/Biotechnology/ucm096095.htm.

<sup>&</sup>lt;sup>87</sup> Strauss & Sax, supra note 82, at 475 (2016) (citing R.A. Herman & W.D. Price, Unintended compositional changes in genetically modified (GM) crops: 20 years of research, 61 J. AGRIC. FOOD CHEM. 11695–701 (2013); H.Y. Steiner et al., Editor's choice: Evaluating the potential for adverse interactions within genetically engineered breeding stacks, 161 PLANT PHYSIOLOGY 1587, 1587–94 (2013), https://www.ncbi.nlm.nih.gov/pmc/articles/PM C3613440/pdf/1587.pdf; A.E. Ricroch, Assessment of GE food safety using '-omics' techniques and long-term animal feeding studies, 30 NATURE BIOTECHNOLOGY 349, 349–54 (2013); J. Schnell et al., A comparative analysis of insertional effects in genetically engineered plants: considerations for pre-market assessments, 24 TRANSGENIC RES. 1, 1–17 (2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4274372/).

<sup>&</sup>lt;sup>58</sup> Strauss & Sax, *supra* note 82, at 476 ("These studies show evidence of far greater structural, epigenetic and gene-expression variation than had been expected, in general, far exceeding those imparted by genetic engineering (e.g., refs. 11,24,25,26).").

<sup>&</sup>lt;sup>89</sup> *Id.* at 476 nn.22 & 24 ("Gene insertion appears to be a small impact by comparison to the ongoing dynamic variation in gene and genome structure during evolution and breeding.").

<sup>&</sup>lt;sup>50</sup> *Id.* ("Extensive transposition, where genes and promoters are moved throughout genomes, and normal mutational processes and DNA repair, provide a

genomes, precise genetic changes, particularly at a single base pair level, create a risk of the increased expression of toxic or allergenic proteins that is close to zero.<sup>91</sup> Put differently, if the more widespread changes to plant genomes through conventional breeding does not increase the expression of toxic of allergenic proteins, then the less invasive and more precise technology used to create food from GMOs should not and does not create greater risk in this area.

The public is heavily weighing in on our food supply—calling for more nutritious food, sustainable farming, and safety. This call for health, safety, and the environment is manifesting itself through labeling laws.<sup>92</sup> People want to know what they are eating.

The problem with labeling laws—labeling food as GMO, non-GMO, organic, etc.—is that the laws do not tell the consumer about the health, safety, or environmental friendliness. Decades of research demonstrate that food from GMOs is as safe as conventional food.<sup>93</sup>

<sup>92</sup> See, e.g., S. Res. 764, 114th Cong. (2016) (enacted) (amending the Agricultural Marketing Act of 1946, 7 U.S.C. 1621 (2012)); H.R. Res. 1599, 114th Cong. (2016) (enacted). See also An Act Relating to the Labeling of Food Produced with Genetic Engineering, VT. STAT. ANN. tit. 9, §§ 3040, 3041 (2014) (effective July 1, 2016); Press Release, Mike Pompeo, U.S. Congressman, Pompeo Applauds Passage of Safe and Accurate Food Labeling Act (July 23, 2015), http://pompeo.house.gov/news/documentsingle.aspx?DocumentID=398519.

<sup>93</sup> Chelsea Snell et al., Assessment of the Health Impact of GM Plant Diets in Long-term and Multigenerational Animal Feeding Trials: A Literature Review, 50 FOOD & CHEMICAL TOXICOLOGY 1134, 1145 (2012); Pamela Ronald, Plant Genetics, Sustainable Agriculture and Global Food Security, 188 GENETICS 11, 12 (2011); Press Release, American Association for the Advancement of Science, Statement by the AAAS Board of Directors on Labeling of Genetically Modified Foods (Oct. 20, 2012), http://www.aaas.org/sites/default/files/migrate/uploads/AAAS\_GM\_statement.pdf [hereinafter Statement by AAAS]; Yan Song et al., Immunotoxicological Evaluation of Corn Genetically Modified with Bacillus thuringiensis Cry1Ah Gene by a 30-day Feeding Study in BALB/c Mice, 9 PLOS ONE 1, 10 (Feb. 10, 2014), http://www.plosone.org/article/info %3Adoi%2F10.1371%2Fjournal.pone.0078566; Yanfang Yuan et al., Effects of Genetically Modified T2A-1 Rice on the GI Health of Rats After 90-day Supplement, 3 SCI. REP. 1, 6-7 (June 11, 2013), http://www.nature.com/srep/2013/130611/srep01962/pdf/ srep01962.pdf; Xueming Tang et al., A 90-Day Dietary Toxicity Study of Genetically Modified Rice T1C-1 Expressing Cry1C Protein in Sprague Dawley Rats, 7 PLOS ONE 1, 6 (Dec. 27, 2012), http://www.plosone.org/article/info%3Adoi%2F10.1371%2F journal.pone.0052507. See also Philip D. Brune et al., Safety of GM Crops: Compositional Analysis, 1 J. AGRIC. & FOOD CHEMISTRY 8243, 8245 (2013); William D. Price & Lynne Underhill, Application of Laws, Policies, and Guidance from the United States and Canada to the Regulation of Food and Feed Derived from Genetically Modified Crops: Interpretation of Composition Data, 1 J. AGRIC. FOOD & CHEMISTRY 8349, 8353 (2013); Declan Butler,

continual source of potential novelty in the kinds and degrees of modification of gene expression throughout the genome.").

<sup>&</sup>lt;sup>91</sup> *Id.* ("Thus, the risk of unintended expression of endogenous toxic proteins from genetic engineering is no greater than conventional breeding, and in most cases far less."); *see also* Conko et al., *supra* note 78, at 493–99.

## SETON HALL LAW REVIEW [Vol. 47:433

Consumers might be surprised to learn that food labeled "organic" does not have a higher safety profile than other types of food and, in some cases, it actually has a lower safety rating.<sup>94</sup> This is because organic farmers use manure as fertilizer, which, when mishandled, creates major safety concerns. Consumers are worried about exposure to pesticides and herbicides, although scientific studies are clear that low-level exposure to the most commonly used pesticides and herbicides creates no risk to human health.<sup>95</sup> The environmental concerns are more difficult to address not because something is GMO, non-GMO or organic, but because farming is inherently non-eco-friendly.<sup>96</sup> The sustainability component is much more nuanced than labeling can tell a consumer.

To understand consumer decision-making, a survey aimed at consumer associations of health, safety, and environmental friendliness with various labels and types of food was conducted.<sup>97</sup> Subjects were asked to rank how healthy, safe, and environmentally-friendly various food products with the labels "organic," "natural," "low fat or fat free," "non-GMO" and "GMO" were compared to each other.<sup>98</sup> The results showed that respondents found all labels to be significantly healthier, safer, and environmentally friendly compared to the label "GMO."<sup>99</sup> In other words, the subjects found the label "GMO" to be associated with less healthy, less safe, and less environmentally friendly food products compared to other labels.<sup>100</sup>

The results of this study provide a number of interesting

*Hyped GM Maize Study Faces Growing Scrutiny*, NATURE INT'L WKLY. J. SCI. (Oct. 10, 2012), http://www.nature.com/news/hyped-gm-maize-study-faces-growing-scrutiny-1.11566 (rejecting paper that found adverse health events in rats fed GM corn).

<sup>&</sup>lt;sup>94</sup> Mischa Popoff et al., Organics versus GMO: Why the debate?, GENETIC LITERACY PROJECT (Oct. 15, 2013), http://www.geneticliteracyproject.org/2013/10/15/ organics-versus-gmo-why-the-debate/; A. Mukherjee et al., Preharvest Evaluation of Coliforms, Escherichia coli, Salmonella, and Escherichia coli O157:H7 in Organic and

Conventional Produce Grown by Minnesota Farmers, 67 J. FOOD PROTECTION 894, 894–900 (2004). <sup>95</sup> See, e.g., Food and Pesticides, ENVTL. PROTECTION AGENCY,

<sup>&</sup>lt;sup>39</sup> See, e.g., Food and Pesticides, ENVTL. PROTECTION AGENCY, https://www.epa.gov/safepestcontrol/food-and-pesticides (last updated Mar. 15, 2016); G.M. Williams et al., Safety Evaluation and Risk Assessment of the Herbicide Roundup and Its Active Ingredient, Glyphosate, for Humans, 31 REG. TOXICOLOGY & PHARMACOLOGY 117, 117 (2000) ("Roundup herbicide does not pose a health risk to humans.").

<sup>&</sup>lt;sup>96</sup> See Henry I. Miller, Why Organic Isn't 'Sustainable', FORBES (Nov. 19, 2014), http://www.forbes.com/sites/henrymiller/2014/11/19/why-organic-isnt-sustainable/2/#9166d235aed9.

<sup>&</sup>lt;sup>97</sup> Sax & Doran, *supra* note 22, at 630–38.

 $<sup>^{98}</sup>$  *Id.* at 633.

<sup>&</sup>lt;sup>99</sup> *Id.* at 634-35.

<sup>&</sup>lt;sup>100</sup> *Id.* 

observations. First, the label "natural" has no regulatory definition.<sup>101</sup> Despite this, respondents associated the label "natural" with health, safety, and environmental friendliness.<sup>102</sup> Second, the scientific consensus is that food from GMOs is as safe as conventional food. The results demonstrate a consumer disconnect with scientific consensus, and suggest that it is important to undertake studies to understand why. Finally, the results suggest that additional studies are needed to understand why consumers inappropriately assign risk to food labeled as GMO.<sup>103</sup>

Affect and ambiguity might help explain consumer perceptions of food created from GMOs. If consumers perceive food created from GMOs as less safe, less healthy or less environmentally friendly, then they might experience a feeling of "badness" when purchasing or eating this food.<sup>104</sup> Conversely, consumers may experience "goodness" when buying food that they believe is safe, healthy, and environmentally friendly, such as organic food. In other words, consumers will want to make decisions that reproduce pleasant feelings, and consumers may be more likely to buy food that satisfies their affective tendencies.<sup>105</sup> Similarly, when consumers feel as though they do not understand GMO technology, they will be unable to assign risk to food created by this technology. Additionally, consumers may have trouble evaluating information in the face of conflicting information from apparently credible sources. In the end, consumers might rather buy conventional food because they can assign a risk to that food, than buy food from GMOs where they perceive that they cannot assign a risk.

Policymakers need to address the multitude of problems facing our food supply. Scientific advances have often been the solution to problems. From a scientific perspective, genetic engineering provides an important avenue to solve food supply issues and address environmental concerns. It would be interesting to determine the outcome if consumers were told that conventional food contains hundreds to thousands of unknown and uncharacterized mutations (which is true), and whether they would still feel as confident in choosing non-GMO over GMO. These types of issues will be explored

<sup>&</sup>lt;sup>101</sup> *Id.* at 635.

<sup>&</sup>lt;sup>102</sup> *Id.* at 634–35.

<sup>&</sup>lt;sup>103</sup> Sax & Doran, *supra* note 22, at 634–35.

<sup>&</sup>lt;sup>104</sup> *Id.* 

<sup>&</sup>lt;sup>105</sup> See Slovic, Risk Perception and Affect, supra note 27, at 322 ("Many theorists have given affect a direct and primary role in motivating behavior. Pleasant feelings motivate actions that people anticipate will reproduce those feelings. Unpleasant feelings motivate actions that people anticipate will avoid those feelings.").

SET

SETON HALL LAW REVIEW

[Vol. 47:433

## in Part III.

# C. rbST

454

Recombinant bovine somatotrophin (rbST) is the injection of a naturally occurring bovine growth hormone, to increase milk production in cows.<sup>106</sup> Two areas of scientific research converged to establish this technique. First, recombinant DNA (rDNA) technology allows scientists to create genes in a laboratory and then produce the proteins therefrom in a bacteria culture.<sup>107</sup> The produced protein is then purified and the result is the man-made version of an otherwise naturally occurring protein. Second, research demonstrated that injecting bovine growth hormone into cows increased their milk production.<sup>108</sup> This bovine growth hormone (bGH or bST) is naturally produced by the pituitary gland.<sup>109</sup> By combining these two areas of research, scientists demonstrated that bGH-also referred to as bovine somatotropin or Sometribove-created through rDNA could be injected into dairy cows to increase milk production.<sup>110</sup> The recombinant forms of the bGH are referred to as rbGH or rbST.<sup>111</sup>

Growth hormones, while naturally occurring in mammals, are tightly regulated within a naturally occurring system.<sup>112</sup> The concern expressed about rbST is whether it has adverse health events in

<sup>&</sup>lt;sup>106</sup> Lorna Aldrich & Noel Blisard, *Consumer Acceptance of Biotechnology Lessons from the rbST Experience*, 747–01 CURRENT ISSUES IN ECON. OF FOOD MKTS. 1, 1 (1998), https://naldc.nal.usda.gov/download/34230/PDF ("[L]aboratory-produced rbST, when injected into cows, increases their milk production.").

<sup>&</sup>lt;sup>107</sup> Anthony J.F. Griffiths, *Recombinant DNA Technology*, ENCYCLOPEDIA BRITANNICA, http://www.britannica.com/science/recombinant-DNA-technology (last updated Apr. 8, 2016).

<sup>&</sup>lt;sup>108</sup> Bovine Somatotropin, ANIMAL & PLANT HEALTH INSPECTION SERVS. (May 2003), https://www.aphis.usda.gov/animal\_health/nahms/dairy/downloads/dairy02/Dairy 02\_is\_BST.pdf ("Repeated studies have demonstrated that administering bST to lactating dairy cattle significantly increases milk production.").

<sup>&</sup>lt;sup>109</sup> See Aldrich & Blisard, supra note 106, at 1 ("BST is a bovine growth hormone that occurs naturally in cows[.]"); see also Is Milk from rbGH-Injected Cows Safe? Why Isn\'t It Labeled?, UCBIOTECH.ORG, http://ucbiotech.org/answer.php?question=37 (last updated Feb. 16, 2012) [hereinafter Is Milk from rbGH-Injected Cows Safe?] ("bGH, produced in the pituitary glands of dairy cows, is a naturally occurring protein hormone in milk, which stimulates the liver to produce insulin-like growth factor-I (IGF-I).").

<sup>&</sup>lt;sup>110</sup> Report on the Food and Drug Administration's Review of the Safety of Recombinant Bovine Somatotropin, U.S. FOOD AND DRUG ADMIN., http://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/uc m130321.htm (last updated July 28, 2014) [hereinafter FDA Report on rBST].

<sup>&</sup>lt;sup>111</sup> See, e.g., Is Milk from rbGH-Injected Cows Safe?, supra note 109.

<sup>&</sup>lt;sup>112</sup> See, e.g., Nathalie Girard et al., Differential in vivo Regulation of the Pituitary Growth Hormone-Releasing Hormone (GHRH) receptor by GHRH in Young and Aged Rats, 140 ENDOCRINOLOGY 2836, 2836 (1999).

humans and cows.<sup>113</sup> Through extensive FDA evaluation and decades of research, it has been shown that "bGH is biologically inactive in humans even if injected, rbGH is orally inactive, and bGH and rbGH are biologically indistinguishable."<sup>114</sup>

In recent years, consumers have been pulled into a medley of debates and concerns among manufacturers. Some manufacturers are utilizing an "rbST-free" label.<sup>115</sup> Monsanto, the big agriculture giant, has sued over this type of labeling—presumably because the label indicates that something is rbST-free because there are health concerns to avoid.<sup>116</sup> Attorneys for Monsanto argued that the FDA recommended that these types of labels be provided in the proper context; for example, "no significant difference has been shown between milk derived from (hormone)-treated and non-(hormone)-treated cows."<sup>117</sup> If, however, a consumer wants to find a negative take on rbST, they can be led to Organic Valley's website to obtain information about the use of rbST.<sup>118</sup>

The labeling debate is indicative of the array of information that consumers receive. If consumers want to learn about the contours of rbST, they will find a broad array of information—some correct, some

<sup>&</sup>lt;sup>113</sup> See Is Milk from rbGH-Injected Cows Safe?, supra note 109.

<sup>&</sup>lt;sup>114</sup> FDA Report on rBST, *supra* note 110.

<sup>&</sup>lt;sup>115</sup> See, e.g., ORGANIC VALLEY, https://www.organicvalley.coop/why-organicvalley/5-reasons-eat-organic/because-our-cows-and-kids-should-grow-their-own-pace/ (last visited Jan. 12, 2017) (citing On the Offense, GRACE COMM. FOUND., http://www.sustainabletable.org/797/rbgh (last visited Nov. 23, 2016)). But see Background on the Public Hearing on the Labeling of Food Made from the AquAdvantage Salmon, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/Food/GuidanceRegulation/ GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm222608.htm (last updated Nov. 19, 2015) (internal citation omitted) ("For example, recombinant Bovine Somatotropin ("rBST") is a synthetic growth hormone that increases milk production in dairy cows. Because FDA found that there was no material difference between milk from rBST-treated cows and milk from non-rBST-treated cows, FDA did not have the authority to require additional labeling of milk from rBST-treated cows.").

<sup>&</sup>lt;sup>116</sup> Susan Q. Stranahan, *Monsanto vs. the Milkman*, MOTHER JONES (Jan/Feb 2004), http://www.motherjones.com/politics/2004/01/monsanto-vs-milkman ("Oakhurst's labels, contends Monsanto, might cause consumers to question the drug's safety, even though the FDA has found that milk from cows injected with rBGH is the same as regular milk and that the hormone poses no human health risks.").

<sup>&</sup>lt;sup>117</sup> Matt Wickenheiser, Oakhurst Sued by Monsanto Over Milk Advertising: Monsanto Objects to the Dairy's Public Stance Against Using Hormones, PORTLAND PRESS HERALD, July 8, 2003, at 1A; see also Bovine Somatotropin, WIKIPEDIA, https://en.wikipedia.org/wiki/ Bovine\_somatotropin (last visited May 25, 2016).

<sup>&</sup>lt;sup>118</sup> Recombinant Bovine Growth Hormone (rBGH): What is it?, ORGANIC VALLEY, http://organicvalley.custhelp.com/app/answers/detail/a\_id/152/kw/rbst/session/ L3RpbWUvMTQ2NDE5NjQzNS9zaWQvSktQbHVvUm0%3D (last visited July 21, 2016) (providing reasons why rBGH is bad for cows, people, and farmers).

## SETON HALL LAW REVIEW [Vol. 47:433

wrong, and some contradictory. Consumers might learn that some data indicates that cows treated with rbST also have elevated levels of insulin-like growth factor-1 (IGF-1), which can be absorbed in a human gut.<sup>119</sup> The increased exposure of IGF-1 in humans raises concerns about increased levels of cancer. Thus, the association of rbST and IGF-1 continues to be promoted as a possible adverse consequence for people who drink milk from cows treated with rbST.<sup>120</sup> Studies show that milk consumption, whether from cows treated with rbST or not, appears to be correlated with increased levels of IGF-1, but no scientific consensus exists regarding causation.<sup>121</sup>

The Center for Food Safety, an apparent activist group, has portions of its website dedicated to rbST.<sup>122</sup> The Center for Food Safety uses a child drinking a glass of milk to not-so-quietly hint about rbST concerns.<sup>123</sup> The Center for Food Safety alleges that cows treated with rbST may also then need antibiotic treatment for the side effects, which subsequently create residues in milk that "can cause allergic reactions in sensitive individuals and contribute to the growth of antibiotic resistant bacteria, further undermining the efficacy of some antibiotics in fighting human infections."<sup>124</sup>

While the Center for Food Safety's representation has a hint of truth, the discussion is more nuanced than how it is presented. A major area of scientific concern is with the health of the cows.<sup>125</sup>

456

<sup>&</sup>lt;sup>119</sup> FDA Report on rBST, *supra* note 110.

<sup>&</sup>lt;sup>120</sup> ORGANIC VALLEY, https://www.organicvalley.coop/why-organic-valley/5reasons-eat-organic/because-our-cows-and-kids-should-grow-their-own-pace/ (last visited Jan. 12, 2017) (click on "Read the Report" under the statement: "Artificial hormone (rBGH / rBST) injections in cows: inhumane and unnecessary").

Recombinant Bovine Growth Hormone, AM. CANCER SOC'Y, http://www.cancer.org/cancer/cancercauses/othercarcinogens/athome/recombin ant-bovine-growth-hormone (last updated Sept. 10, 2014) ("The evidence for potential harm to humans is inconclusive."); see also FDA Report on rBST, supra note 110 ("It bears repeating that the assumptions that milk levels of IGF-I are increased following treatment with rbGH and that biologically active IGF-I is absorbed into the body are not supported by the main body of science. Careful analysis of the published literature fails to provide compelling evidence that milk from rbGH-treated cows contains increased levels of IGF-1 compared to milk from untreated cows. Despite recent studies that demonstrate that milk proteins protect IGF-I from digestion, the vast majority of the published work indicates that very little IGF-I is absorbed following ingestion.").

<sup>&</sup>lt;sup>122</sup> *About rbGH*, CTR. FOR FOOD SAFETY, http://www.centerforfoodsafety.org/issues/ 1044/rbgh/about-rbgh (last visited May 25, 2016).

 $<sup>^{123}</sup>$  Id.

<sup>&</sup>lt;sup>124</sup> *Id.* 

<sup>&</sup>lt;sup>125</sup> I.R. Dohoo et al., A Meta-Analysis Review of the effect of Recombinant Bovine Somatotropin, 2. Effects on animal Health, Reproductive Performance and Culling, 67 THE CANADIAN J. OF VETERINARY RES. 252, 253 (2003).

Treatment with rbST is associated with mastitis, which is an infection of the breast tissue.<sup>126</sup> Treatment of mastitis includes the use of antibiotics.<sup>127</sup>

The array of information regarding rbST creates challenges for consumers to appropriately assign risk to this application of biotechnology. If consumers perceive that treatment of cows with rbST causes cancer in humans, then consumers will assign a high risk. Likewise, if consumers perceive that children will be harmed by drinking milk from cows treated with rbST, then they will experience "badness" with an associated decision. The varying information on the Internet about rbST creates issues for consumer decision-making because consumers may not be able to appropriately assign risk.

The rbST and GMO debates underscore the need for a robust discussion about how we use science to improve our food supply and agriculture techniques. If consumers have concerns, they should be addressed. It is important, however, that the concerns and assignment of risk are based on accurate information. If information is lacking, studies in these areas should be initiated. In Part III, below, this article proposes studies aimed at understanding if and how consumers are responding to conflicting information on the Internet.

#### D. Fluoridated Water

Touted as one of the greatest public health achievements in the 20th Century, fluoridated water significantly decreases cavities, tooth decay and tooth loss in children and adults.<sup>128</sup> Fluoridated water refers to the addition of fluoride to the public water supply. Tooth decay is a major public health problem due to the medical concern that tooth decay impairs eating, but also because of the cosmetic effect on societal acceptance.<sup>129</sup> Overall, the cost to fluoridate water is much less

<sup>&</sup>lt;sup>126</sup> *Id.* at 252 ("Recombinant bovine somatotropin was found to increase the risk of clinical mastitis by approximately 25% during the treatment period but there was insufficient data to draw firm conclusions about the effects of the drug on the prevalence of subclinical intra-mammary infections.").

<sup>&</sup>lt;sup>127</sup> Walter L. Hurley, *Mastitis Case Studies Mastitis Treatment and Control*, http://ansci.illinois.edu/static/ansc438/Mastitis/control.html (last visited May 24, 2016) ("Typically when clinical mastitis is detected, the cow is milked out and then given an intramammary infusion of antibiotic, ie. infused directly into the infected gland.").

<sup>&</sup>lt;sup>128</sup> *Fluoridation Basics*, CTR. FOR DISEASE CONTROL, http://www.cdc.gov/fluoridation/basics/ (last updated July 28, 2015) [hereinafter CDC, *Fluoridation Basics*].

<sup>&</sup>lt;sup>129</sup> *Id.*; *see also Water Fluoridation*, WIKIPEDIA, https://en.wikipedia.org/wiki/Water\_fluoridation (last visited May 25, 2016).

SETON HALL LAW REVIEW

[Vol. 47:433

expensive than the treatment for cavities.<sup>130</sup>

The only known adverse effect associated with fluoridated water is dental fluorosis, which is a mild condition, usually found on children's teeth that alters the appearance.<sup>131</sup> Dental fluorosis is not a public health concern and can be tempered by monitoring fluoride intake, including toothpaste.<sup>132</sup> Over exposure to fluoride is associated with minor adverse health effects, which means that fluoridation is tightly monitored and adjusted.<sup>133</sup> Decades of research demonstrate that fluoride levels in the 0.7 milligrams of fluoride per liter of water range have the desired public health benefit and have a low risk of causing dental fluorosis.<sup>134</sup>

The Center for Disease Control, the American Dental Association and the American Medical Association all support fluoridated water programs based on the widespread dental health benefits. Economic analysis found that for "every \$1 invested in this preventative measure yields approximately \$38 savings in dental treatment costs."<sup>135</sup>

Not immune from controversy, opponents to fluoridated water challenge the science and efficacy. Some communities in the US are moving towards or are enacting non-fluoridation programs. In Portland, Oregon, for example, voters defeated a plan to add fluoride to the public water supply.<sup>136</sup>

Similar to the above examples, an Internet search reveals a wide array of information. Consumers can find allegations that fluoridation is linked to AIDS.<sup>137</sup> This does not make sense given that AIDS is caused

<sup>&</sup>lt;sup>130</sup> CDC, *Fluoridation Basics, supra* note 128.

<sup>&</sup>lt;sup>131</sup> *Fluoridation Safety*, CTR. FOR DISEASE CONTROL, http://www.cdc.gov/fluoridation/safety/index.htm (last updated May 13, 2015) ("Dental fluorosis is a change in the appearance of the tooth's enamel. These changes can vary from barely noticeable white spots in mild forms to staining and pitting in the more severe forms.").

<sup>&</sup>lt;sup>132</sup> FAQs for Dental Fluorosis, CTR. FOR DISEASE CONTROL, http://www.cdc.gov/fluoridation/safety/dental\_fluorosis.htm#a9 (last updated Aug. 31, 2015).

<sup>&</sup>lt;sup>133</sup> *Id.* 

<sup>&</sup>lt;sup>134</sup> *Community Water Fluoridation*, CTR. FOR DISEASE CONTROL, http://www.cdc.gov/fluoridation/faqs/ (last updated July 28, 2015).

<sup>&</sup>lt;sup>130</sup> Cost Savings of Community Water Fluoridation, CTR. FOR DISEASE CONTROL, https://www.cdc.gov/fluoridation/factsheets/cost.htm (last updated July 10, 2013).

<sup>&</sup>lt;sup>130</sup> Douglas Main, *Facts About Fluoridation*, LIVESCIENCE (Apr. 30, 2015), http://www.livescience.com/37123-fluoridation.html ("For the fourth time since 1956, voters in Portland defeated a plan in 2012 to add fluoride to the public water supply.").

<sup>&</sup>lt;sup>137</sup> See, e.g., Water Fluoridation Controversy, WIKIPEDIA, https://en.wikipedia.org/wiki /Water\_fluoridation\_controversy (last visited May 25, 2016) ("Antifluoridationist literature links fluoride exposure to a wide variety of effects, including AIDS, allergy, Alzheimer's disease, arthritis, cancer, and low IQ, along with diseases of the gastrointestinal tract, kidney, pineal gland, and thyroid.").

by a virus and fluoride is an element. Moreover, a person cannot contract HIV/AIDS by drinking water. Action groups against fluoridated water programs also exist online. Fluoride Action Network, for example, provides three main reasons to oppose fluoridated water programs: (1) outdated mass medication; (2) unnecessary and ineffective; and (3) unsafe.<sup>138</sup> It is clear from reviewing the Fluoride Action Network website that fear is the main motivator to influence opposition to fluoridated water. This website strongly suggests that the government is administering drugs to people against their will. Additionally, according to this group, there is no benefit to fluoride and the risk of developing disease is high.<sup>139</sup>

Given that consumers receive a wide array of information regarding the safety and efficacy of fluoridated water programs, it is not surprising that consumers may not appropriately assign risk to these programs. If, for example, consumers perceive that there might be long-term deleterious consequences from fluoridated water, they will inappropriately assign risk to community fluoridation programs. Similarly, if consumers perceive the benefit as low, they might assign a high risk to these programs. In addition, consumers may associate "goodness" or "badness" with decisions to reject or embrace widespread fluoridation programs.

#### E. Embryonic Stem Cell Research

Unlike the above examples, this area of biotechnology raises a different issue—that of research funding. The areas above are already in the implementation and application stages. While some clinical trials are in progress, embryonic stem cell research is in a more infant stage and will require major sources of funding to capture its full potential. In this controversial area of research, consumers were explicitly called on to be part of the conversation and assist in the decision as to whether the federal government should fund embryonic stem cell research.

By way of background, in the 1990s, scientists began hypothesizing that they could harness the plasticity of embryonic stem cells to treat disease.<sup>140</sup> Embryonic stem cells are early progenitor cells

<sup>&</sup>lt;sup>138</sup> Water Fluoridation, FLUORIDE ALERT, http://fluoridealert.org/issues/water/ (last visited Oct. 31, 2016).

<sup>&</sup>lt;sup>139</sup> See id.

<sup>&</sup>lt;sup>140</sup> Stem Cell Information: Stem Cell Basics, NAT'L INSTS. OF HEALTH, https://stemcells.nih.gov/info/basics/1.htm (last visited Dec. 31, 2016) [hereinafter NIH STEM CELL INFORMATION].

## SETON HALL LAW REVIEW [Vol. 47:433

that have the ability to turn into many different cell types.<sup>141</sup> Cell signals are given to these early progenitor cells to tell them to become muscle, organ, neural or skeletal cells.<sup>142</sup> Since many human ailments are characterized by a loss of function of particular cells, the idea was that the diseased cells could be replaced by non-diseased cells.<sup>143</sup> Put differently, if an individual's pancreas, for example, has problems with insulin producing cells, the patient could be treated with a stem cell therapy to replace the diseased pancreatic cells with healthy pancreatic cells. This similar, hypothetical approach could be used to treat major ailments such as Parkinson's disease, Alzheimer's Disease, muscular dystrophy, and others.<sup>144</sup>

Controversy ensued regarding the starting material for embryonic stem cell research, which is fertilized eggs—created *in vitro*.<sup>145</sup> Opponents to embryonic stem cell research claimed that the fertilized eggs had the *potential* for human life, thus this type of research was unethical.<sup>146</sup> Proponents of embryonic stem cell research looked at the fertilized eggs as cells and also promoted the potential to treat disease.<sup>147</sup> Some consumers may sit in the middle of this debate—that is, they may not personally have a moral objection, but they may be sympathetic to others who do. Thus, while a large part of the debate has value-based or religious undertones, some portion of the debate is likely more nuanced than any particular value-based belief.

The debate about whether the federal government should fund embryonic stem cell research came to a head in 2001 under President George W. Bush.<sup>148</sup> To address this topic, President Bush relied heavily on the Presidential Commission for Bioethics.<sup>149</sup> This panel advises the President on bioethical issues.<sup>150</sup> Leon Kass, the Chair of the Commission, took center stage during this debate for his views against

<sup>148</sup> Sax, *The States "Race" with the Federal Government, supra* note 143, at 15.

<sup>149</sup> *Id.* at 16.

<sup>&</sup>lt;sup>141</sup> *Id.* 

 $<sup>^{142}</sup>$  Id.

<sup>&</sup>lt;sup>143</sup> Joanna K. Sax, *The States "Race" with the Federal Government*, 15 ANNALS OF HEALTH L. 1, 8 (2006) [hereinafter Sax, *The States "Race" with the Federal Government*].

Id.

<sup>&</sup>lt;sup>145</sup> Id. at 9 (citing Allen M. Spiegel & Gerald D. Fischbach, NIH Statement Before Senate Appropriations Subcommittee, NAT'L INSTS. OF HEALTH (Apr. 26, 2000), https://stemcells.nih.gov/policy/statements/State.htm).

<sup>&</sup>lt;sup>140</sup> Joanna K. Sax, *The Separation of Politics and Science*, 7 STAN. J.L. SCI. & POL'Y 10, 16 (2014) [hereinafter Sax, *The Separation of Politics and Science*].

 $<sup>^{14&#</sup>x27;}$  Id.

<sup>&</sup>lt;sup>150</sup> About the Commission, PRESIDENTIAL COMMISSION FOR THE STUDY OF BIOETHICAL ISSUES, http://bioethics.gov/about (last visited May 25, 2016).

the funding of embryonic stem cell research.<sup>151</sup> Elizabeth Blackburn, who was not reappointed to the Presidential Commission for Bioethics during this time, charged the administration with stacking the Commission with members who aligned with Leon Kass.<sup>152</sup> It was a political debate.

During this time, the issue of whether to provide federal funding to research embryonic stem cells was heavily publicized and divisive, with a lot of press in both mainstream newspapers as well as in scientific journals.<sup>153</sup> In many ways, the issue was raised as a moral issue to which some politicians wanted constituent feedback. As a representative democracy, this should seem copasetic with our political process.

Given the highly publicized and politicized nature of the issue of federal funding for embryonic stem cell research, one study analyzed the type of information provided to the public regarding embryonic stem cell research.<sup>154</sup> A major contention during this time was whether scientists could use adult stem cells to achieve the same results as embryonic stem cells and thus avoid needing to use the controversial starting material.<sup>155</sup> Scientists contended that they could not make this determination unless and until experiments on both adult and embryonic stem cells were conducted.<sup>156</sup> Some articles in mainstream newspapers, however, reported that adult stem cells might provide equivalent starting material as embryonic stem cells.<sup>157</sup> This reporting occurred at different frequencies in different newspapers, but nevertheless, the information was conveyed to the public.

The reporting of different information, either that adult stem cells are not equal to embryonic stem cells, or that adult stem cells might be equal to embryonic stem cells, creates ambiguity. How is a typical consumer going to weigh that information? Those with a moral opposition to embryonic stem cell research might perceive the information differently than those without a moral opposition. That is, a person may not be personally opposed to the research, but s/he may be sympathetic to those who are. If people perceive that a workable compromise exists, i.e., only performing research on adult stem cells since they are likely to provide the same information, then they will make a decision accordingly. Put differently, even those

<sup>&</sup>lt;sup>151</sup> Sax, *The States "Race" with the Federal Government, supra* note 143, at 17.

 $I_{153}^{152}$  Id.

<sup>&</sup>lt;sup>103</sup> See, e.g., Sax, The Separation of Politics and Science, supra note 146, at 8–10.

<sup>&</sup>lt;sup>154</sup> *Id.* at 7–14.

<sup>&</sup>lt;sup>155</sup> *Id.* at 8–9.

<sup>&</sup>lt;sup>156</sup> *Id.* at 9.

<sup>&</sup>lt;sup>157</sup> *Id.* at 12.

# SETON HALL LAW REVIEW [Vol. 47:433]

without a moral opposition to embryonic stem cell research might be impartial to a decision not to fund embryonic stem cell research given information that a different starting material might give the same results.

Similarly, affect can impact how consumers view funding of controversial research. Consumers, for example, might experience "badness" at the thought of funding embryonic stem cell research. Whereas other consumers might experience "goodness" at the thought of the decision to support research that has the potential to treat debilitating disease(s).

In 2001, President Bush signed an executive order that placed a practical ban on the funding of embryonic stem cell research.<sup>158</sup> In 2009, with a leadership change, President Obama changed course and allowed federal funding for the creation and experimentation on new stem cell lines.<sup>159</sup>

As articulated elsewhere, changes in funding that appear to be dependent on the administration in charge creates major issues for scientific inquiry and innovation.<sup>160</sup> Putting aside the issues with funding, this example has similarities with the other biotechnology examples discussed above. Here, the consumers are asked to make decisions when there may be incomplete, or even incorrect, information provided—thus incorporating ambiguity. On top of that, controversial research may incorporate feelings of goodness or badness with a decision.

By way of more explicit analogy, the discussion regarding vaccinations (*supra* Part II.A) has many similarities to the issues with funding embryonic stem cell research. First, consumers can search for and obtain a wide amount of information about either issue on the Internet. For example, an Internet search might provide misinformation that vaccines cause autism and embryonic stem cell research is the same thing as an abortion.<sup>161</sup> Conversely, an Internet

462

<sup>&</sup>lt;sup>158</sup> Sax, *The States "Race" with the Federal Government, supra* note 143, at 15.

<sup>&</sup>lt;sup>159</sup> Removing Barriers to Responsible Scientific Research Involving Human Stem Cells, 74 Fed. Reg. 10,667 (Mar. 11, 2009).

<sup>&</sup>lt;sup>160</sup> Sax, *The Separation of Politics and Science, supra* note 146, at 11–14.

<sup>&</sup>lt;sup>161</sup> Arjun Walia, 22 Medical Studies that Show Vaccines Can Cause Autism, ACTIVIST POST (Sept. 12, 2013), http://www.activistpost.com/2013/09/22-medical-studies-that-showvaccines.html; Stem Cell Research, SOC'Y FOR THE PROTECTION OF UNBORN CHILD., https://www.spuc.org.uk/abortion/embryo-abuse/stem-cell-research (last visited May 24, 2016). But see Vaccines Do Not Cause Autism, CTR. FOR DISEASE CONTROL, http://www.cdc.gov/vaccinesafety/concerns/autism.html (last updated Nov. 23, 2015); Myths and Misconceptions about Stem Cell Research, CAL. INST. FOR REGENERATIVE MED., https://www.cirm.ca.gov/patients/myths-and-misconceptions-about-stem-cellresearch (last visited May 24, 2016) ("Embryonic stem cells only come from four

search might provide information that vaccines save lives and that embryonic stem cell research will be a key to treating individuals with Alzheimer's Disease.<sup>162</sup> Consumers in both of these situations will be evaluating inconsistent and even contradictory information, which makes it difficult to assign risk to a particular outcome. Similarly, given the emotionally laden undertone of these controversial areas, consumers may experience "goodness" or "badness" with any particular decision.

Widespread applications of biotechnology do not have the ability to satiate all individual concerns and preferences. In other words, fluoridated water programs cannot indicate which homes would support the programs versus those which would not, because the public water supply is supplied to each home. Vaccination programs require requisite levels of herd immunity to be effective. Embryonic stem cell research is either funded or not. The issue then becomes: how do policymakers not only separate the wheat from the chaff, but also provide information to consumers so that they can appropriately assign risk to new applications of biotechnology? This article turns to this issue in Part III.

#### III. CONSUMER DECISION-MAKING AND POLICY

Understanding consumer decision-making is important when drafting and implementing policies. Research in decision-making informs us that consumers may not appropriately assign risk to an outcome when there are unknowns. In addition, consumers tend to be more sensitive to information about possible risks than to information about potential benefits.<sup>163</sup> Studies show that consumers are skeptical of information provided by pharmaceutical companies (vaccines, rbST, and fluoridated water), agriculture companies (GMOs), and often even scientists (embryonic stem cell research).<sup>164</sup>

to five day old blastocysts or younger embryos.").

<sup>&</sup>lt;sup>162</sup> See, e.g., Stem Cell Research, ALZHEIMER'S SOC'Y, https://www.alzheimers.org.uk/ site/scripts/documents\_info.php?documentID=1039 (last updated August 2012).

<sup>&</sup>lt;sup>103</sup> Montserrat Costa-Font & Jose M. Gil, *Does Expert Trust and Factual Knowledge Shape Individual's Perception of Science*?, 36 INT'L J. CONSUMER STUD. 668, 670 (2012).

<sup>&</sup>lt;sup>104</sup> See, e.g., Mark Kessel, Restoring the Pharmaceutical Industry's Reputation, 32 NATURE BIOTECHNOLOGY 983, 983 (2014); Maria Altman, Monsanto Appeals Directly to Consumers in New Ad Campaign, ST. LOUIS PUBLIC RADIO (Nov. 5, 2014), http://news.stlpublicradio.org/post/monsanto-appeals-directly-consumers-new-adcampaign; Michael McNichol & Zubin Master, Ethical and Scientific Issues Towards the Successful Translation of Stem Cell Research, BIOETHICS TODAY (Jan. 27, 2014), http://www.amc.edu/BioethicsBlog/post.cfm/ethical-and-scientific-issues-towardsthe-successful-translation-of-stem-cell-research ("Several social science studies have shown that patients and the general public trust research done in the public sphere

SETON HALL LAW REVIEW [Vol. 47:433]

On top of this, information regarding technology is imperfect due to degrees of scientific uncertainty.<sup>165</sup> Utilizing communication tactics to explain the unknowns or to allow information to be less ambiguous may assist consumers in assigning risk to a particular decision.

Recent scholarship in this area suggests that providing information to consumers in a manner consistent with decisionmaking theories may assist consumers in assigning risk.<sup>166</sup> In a recent study, Costa-Font and Gil made a number of interesting observations.<sup>167</sup> Understanding the science, for example, was associated with a lower perception of risk. Conversely, a lack of understanding of the underlying science was associated with higher perceptions of risk.<sup>168</sup> This supports the idea that consumers perceive risks as high when there is either not enough information or the information is ambiguous.<sup>169</sup> Perhaps not surprisingly, Costa-Font and Gil also found that trust in the expert conveying the information was important to consumers.<sup>170</sup>

It might seem easy enough to say that trusted experts should provide the scientific information and that this will lead consumers to be in a better position to assign risk. Scientists, however, are not classically trained to translate their discoveries to the general public.<sup>171</sup> The problem with this approach is that not only is it not working but there are forces that actively oppose it. Marketing professionals, for example, frequently exploit the nuances of consumer decisionmaking.<sup>172</sup> The organic food industry, for example, may actively use

<sup>170</sup> *Id.* at 675.

<sup>(</sup>e.g., publically funded universities and colleges), and are less trustworthy of research performed in private and commercial institutions e.g., pharmaceutical or biotech industry. While these same studies also indicate that the public is more than willing to participate in stem cell research by donating tissues, some still don't like the idea of a company making profit and the volunteers not seeing any direct benefit from their participation in research.").

<sup>&</sup>lt;sup>bb</sup> Costa-Font & Gil, *supra* note 163, at 670.

<sup>&</sup>lt;sup>166</sup> *Id.* at 673.

 $<sup>^{167}</sup>$  Id.

<sup>&</sup>lt;sup>168</sup> *Id.* 

 $<sup>^{169}</sup>$  Id.

<sup>&</sup>lt;sup>171</sup> See Center for Public Engagement with Science & Technology, AM. ASS'N FOR THE ADVANCEMENT OF SCI., http://www.aaas.org/pes/communicatingscience (last updated Nov. 3, 2016) [hereinafter AAAS].

<sup>&</sup>lt;sup>172</sup> See Slovic, What's Fear Got to Do with It?, supra note 36, at 983 ("There are two important ways that experiential thinking misguides us. One results from the deliberate manipulation of our affective reactions by those who wish to control our behaviors. (Advertising and marketing exemplify this manipulation). The other results from the natural limitations of the experiential system and the existence of stimuli in our environment that are simply not amenable to valid affective representation.").

affect and ambiguity to scare consumers away from food produced from GMOs. Put differently, the organic food industry has an economic interest to entice consumers to buy organic food and not to buy food from GMOs. By making consumers feel "goodness" about organic food and "badness" about food from GMOs, the organic industry can exploit consumer decision-making.

A recent study by Hughner and colleagues analyzed which types of individuals are organic food consumers.<sup>173</sup> In surveying several studies, they identified certain demographics that stand out: organic food consumers tend to be female, have children, and are older, though these characteristics are not mutually exclusive of each other.<sup>174</sup> Research also suggested that organic food consumers see their preference associated with a "way of life" and with an ideology.<sup>175</sup> Hughner and colleagues articulated nine themes associated with consumer motivations and six themes associated with consumer deterrents when deciding whether to purchase organic food.<sup>176</sup> The motivations included: (1) healthier; (2) tastes better; (3) environmental concern; (4) concern over food safety; (5) concern over animal welfare; (6) supports local economy and sustain traditional cooking; and (7-9) wholesome, reminiscent of the past, and fashionable.<sup>177</sup> Deterrents included: (1) high prices; (2) lack of availability; (3) skepticism of certification boards and labels; (4) insufficient marketing; (5) satisfaction with current food source; and (6) cosmetic defects.<sup>17</sup>

A recent study showed that survey participants perceive that organic farmers care more about health, safety, and environmental friendliness compared to conventional or GMO farmers.<sup>179</sup> Likewise, participants also perceive that farmers who grow GMO crops care more about efficiency (and less about health, safety, and the environment) compared to organic farmers.<sup>180</sup> This perception is unlikely to be resolved by statements or advertisements by Monsanto (a major supplier of genetically engineered seeds), especially given consumer mistrust of some big corporations.<sup>181</sup> Interestingly, it may be that large-scale industrial farms are more environmentally friendly given that

<sup>178</sup> *Id.* at 103–04.

 $^{180}$  Id.

<sup>&</sup>lt;sup>173</sup> Hughner et al., *supra* note 72, at 94.

<sup>&</sup>lt;sup>174</sup> *Id.* at 96.

 $<sup>^{175}</sup>$  *Id.* 

<sup>&</sup>lt;sup>176</sup> *Id.* at 101–04.

<sup>&</sup>lt;sup>177</sup> *Id.* at 101–03.

<sup>&</sup>lt;sup>179</sup> Sax & Doran, *supra* note 22.

<sup>&</sup>lt;sup>81</sup> See Altman, supra note 164.

SETON HALL LAW REVIEW [Vol. 47:433]

they have the capacity to invest in technology that tends to be more "gentl[e] on the environment."<sup>182</sup>

The information containing the scientific consensus about the various technologies discussed in this article is available for the public to read. The Center for Disease Control, for example, provides information about the safety and efficacy of vaccines.<sup>183</sup> It is not just that the information be provided in order for the consumer to make a decision—that is not sufficient. This is because a consumer can perform an Internet search on "vaccines and autism" and locate information, albeit incorrect, about a link between the two. Thus, consumers receive contradictory and ambiguous information, and they don't know how to appropriately wade through all of it.<sup>184</sup> In this example, if a parent believes that his/her child might become autistic due to vaccinations, s/he will feel "badness" in making a decision to vaccinate. Therefore, the method of communication must take into account affect and ambiguity, especially as we are in the information age.

Even major scientific reports are unlikely to resolve the mass amount of contradictory information provided to consumers. In May 2016, the National Academies of Science released a comprehensive report about the health, safety and environmental friendliness of genetically engineered food.<sup>185</sup> Through a painstaking review of the relevant literature, the National Academies of Science concluded the following:

(1) Effect on Environment: "Overall, the committee found no evidence of cause-and-effect relationships between GE crops and environmental problems."<sup>186</sup>

(2) Human Health: "[T]he research that has been

<sup>&</sup>lt;sup>182</sup> Jayson Lusk, *Why Industrial Farms are Good for the Environment*, N.Y. TIMES, Sept. 25, 2016, at SR4, http://www.nytimes.com/2016/09/25/opinion/sunday/why-industrial-farms-are-good-for-the-environment.html?\_r=0.

<sup>&</sup>lt;sup>183</sup> CDC, *Vaccine Safety, supra* note 48.

<sup>&</sup>lt;sup>184</sup> But see George Johnson, The Widening World of Hand-Picked Truths, N.Y. TIMES (Aug. 24, 2015), http://www.nytimes.com/2015/08/25/science/the-widening-world-of-hand-picked-truths.html?\_r=0 ("Google recently tweaked its algorithm so that searching for 'vaccination' or 'fluoridation,' for example, brings vetted medical information to the top of the results.").

<sup>&</sup>lt;sup>185</sup> National Academy of Sciences, *Genetically Engineered Crops: Experiences and Prospects*, THE NAT'L ACADEMIES PRESS (May 17, 2016), http://www.nap.edu/catalog/23 395/genetically-engineered-crops-experiences-and-prospects [hereinafter N.A.S., *Genetically Engineered Crops*]; see also Henry I. Miller, National Academy of Sciences 'GMO' Report Does Science no Favors, FORBES (May 24, 2016, 5:00 AM), http://www.forbes.com/sites/henrymiller/2016/05/24/national-academy-ofsciences-gmo-data-dump-leaves-over-regulation-intact/#151a8d347a0b.

<sup>&</sup>lt;sup>6</sup> N.A.S., *Genetically Engineered Crops, supra* note 185, at 100.

conducted in studies with animals and on chemical composition of GE food reveals no differences that would implicate a higher risk to human health from eating GE foods than from eating their non-GE counterparts."<sup>187</sup>

(3) Social and Economic Effects: "[E]xisting GE crops have generally been useful to large scale farmers of cotton, soybean, maize and canola. The same GE crops have benefitted a number of small-scale farmers, but benefits have varied widely across time and space, and are connected to the institutional context in which the crops have been deployed."<sup>188</sup>

The National Academies Report essentially regurgitated much of what scientists have known for a long time, but was equivocal at times, citing the need for additional studies.<sup>189</sup> Since the scientific process necessarily leads to additional questions, some familiar in this field have suggested that the calls for additional studies can be taken out of context.<sup>190</sup> Put differently, just because additional studies are needed does not mean that we do not know enough to implement sensible policies and regulations.

The issue is not only how to communicate the science of the technology so that consumers have the factual information to appropriately assign risk, but also how to combat false, ambiguous, or misleading information. Since ambiguous information is available on the Internet, it is not possible to provide only accurate information to consumers. Instead, different platforms must be created to provide correct information in a way that considers how consumers make decisions.

Dread is an important feeling involved with risk perception.<sup>191</sup> Recent studies demonstrate that "perceptions of risk and society's responses to risk were strongly linked to the degree to which a hazard evoked feelings of dread. Thus, activities associated with cancer are seen as riskier and more in need of regulation than activities associated with less dreaded forms of illness, injury, and death (e.g., accidents)."<sup>192</sup> Other studies analyzing the role of affect in decision-making show an inverse relationship: "judgments of risk and benefit are negatively

<sup>192</sup> Id.

<sup>&</sup>lt;sup>187</sup> Id. at 156.

<sup>&</sup>lt;sup>188</sup> *Id.* at 221; *see also* Strauss & Sax, *supra* note 82, at 476 (discussing how the time and cost of the regulatory process impedes small farmers from taking advantage of the technology).

<sup>&</sup>lt;sup>189</sup> Miller, *supra* note 185.

<sup>&</sup>lt;sup>190</sup> *Id.* 

<sup>&</sup>lt;sup>191</sup> Slovic, *The Affect Heuristic, supra* note 14, at 1342 (internal citation omitted).

## SETON HALL LAW REVIEW [Vol. 47:433

correlated."<sup>193</sup> Results from studies showing this inverse relationship suggest that "people base their judgments of an activity or a technology not only on what they *think* about it but also what they *feel* about it. If they like an activity, they are moved to judge the risks as low and the benefits as high; if they dislike it, they tend to judge the opposite: high risk and low benefit."<sup>194</sup>

Another potential problem for policies that implement technology is the recognition that scientific theories and paradigms change over time. Science is about asking questions and testing hypotheses. This process leads to major paradigm upheavals (compare Newton to Einstein) and even smaller paradigm shifts (eating high-fat food is not as bad as was once thought). To be fair, even if the correct information is provided to consumers in a way that allows them to assign risk, the application of scientific discovery will (and should) face some healthy skepticism, especially given the incremental changes and paradigm shifts. However, overall we live longer and healthier lives compared to previous generations. So, the fear of the potential unknowns in science should be evaluated within this larger context.

So, where do we go from here? This article proposes several approaches for policymakers to consider, all of which use decisionmaking theories to assuage consumer concerns, allow consumers to appropriately assign risk, and to make informed decisions. These suggestions promote studying the influence and role of affect and ambiguity as a component to drafting, adopting, and implementing policy. Affect and ambiguity have not played a major role in the legal policy arena.<sup>195</sup> The studies described in Part II support the hypothesis that affect and ambiguity are playing a role in how consumers are responding to policies that implement biotechnology. Given that the examples described in Part II-vaccines, GMOs, rbST, fluoridated water, and embryonic stem cell research-are not controversial within the scientific community, it is important to understand why consumers perceive risks so differently than the experts. With large-scale problems, such as climate change and health care, needing to be

468

 $<sup>^{193}</sup>$  Id.

<sup>&</sup>lt;sup>194</sup> *Id.* at 1343.

<sup>&</sup>lt;sup>195</sup> See Peters et al., *supra* note 36, at 79 (citation omitted) ("The field of judgment and decision making (JDM) long neglected the influence of 'hot processes' on decision behavior in favor of a focus on 'cold,' deliberative, and reason-based decision making. Historically, this was due at least in part to hot processes being viewed primarily as biased, leading to irrational choice behavior. However, over the last ten years the JDM field has turned its attention more and more to how affective feelings influence judgments and decisions. Today, emotion and affect are on the research agenda for many JDM researchers.").

addressed, consumers' perceptions of risk must come closer to the actual risks as evaluated by experts. Otherwise, this tension will likely increase and lead to the same type of rejection that has occurred with nuclear energy.<sup>196</sup>

Based on the information described above, this article articulates four themes that consider both what we already know and where we should consider going. All four of these themes posit that affect and ambiguity play important roles in obtaining consumer support for policy implementation. Within each theme, this article describes examples of possible future directions for studies by using vaccines, GMOs, rbST, fluoridated water, and embryonic stem cell research as test cases. This article briefly proposes examples of pilot studies that can be conducted. While the general outline of ways to examine the themes are discussed below, detailed studies that utilize software suites dedicated to behavioral studies, large-scale consumer analyses and other approaches could form the basis for grant applications and potentially funded studies. The below discussion is meant to open a dialogue and conversation for future directions and collaborations.

Some of the themes below have overlapping concerns for policy implementation. An example of an overlapping concern is how to address consumer autonomy in public health policy implementation, such as vaccinations and fluoride in the water supply. On the other hand, each area of technology poses individual or unique concerns. recombinant DNA technology forms the underlying While technological basis for both rbST and GMOs, these areas of biotechnology face independent challenges in policy implementation. To address the overlapping and individual issues, each example is discussed within each of the themes. To highlight the differences, this article suggests ways to conduct studies to test whether and how each theme might apply to each example. The purpose of this is to stress that: (1) a one-approach-fits-all will not work for implementation of controversial areas of technology; and (2) future studies catered towards each example that test the role of affect and ambiguity can be conducted. The next few subsections are forward-thinking in that the discussion herein can form the basis of future empirical studies.

<sup>&</sup>lt;sup>6</sup> See Walsh, supra note 11.

SETON HALL LAW REVIEW [Vol. 47:433

## A. Theme 1: Separate the Wheat from the Chaff: Allow Consumers to make Informed Choices

First, informed decisions should be based on accurate information.<sup>197</sup> This problem is starkly seen in the vaccination wars. VHPs resist vaccination based on concerns of linkage to autism, irreversible harm, low likelihood of contracting the actual disease, and perhaps an incorrect understanding of the devastating impact of the vaccine-preventable disease.<sup>198</sup> These beliefs are based on inaccurate information; thus, the consumers are not making informed decisions. While individual autonomy regarding the decision to vaccinate or not presents major public health challenges, due to the requirement for herd immunity, it may be possible to soften the resistance to simply by providing consumers with accurate vaccinations Studies should be aimed at testing how to provide information. accurate information to consumers in a way that allows them to appropriately assign risk. An example of a specific study could test whether environmental differences impact how consumers receive and process information. For example, would a mobile-nurse (or other health care professional) visiting a family in their home to both provide information and answer questions have an impact on decisionmaking, as compared to no home visit? Or, perhaps, could literature about vaccines be provided via U.S. Mail prior to a doctor's visit to assist with providing accurate information to consumers? These prior visits or mailings could be presented with a "happy" inference such that consumers may experience some sort of positive feeling associated with This could be compared to simply providing the information. information at a doctor's visit. This type of study incorporates both affect and ambiguity in analyzing how consumers respond to the presentation of accurate information.

In the debate surrounding GMOs, food labeling laws provide a helpful example in which consumers seek to make informed decisions. If consumers want to know information about their food, including the source, then food labeling laws can respond to consumer needs. During the past several years, at least thirty-five states have introduced food labeling laws related to genetically engineered food.<sup>199</sup> These laws

<sup>197</sup> See Slovic, What's Fear Got to Do with It?, supra note 36, at 989 ("It seems obvious that designers of risk education and communication programs should work with experts in these fields, yet this does not seem to be happening. Such collaboration would help the government to work with the intended audience of each message. Designers need to listen to the public's concerns, collaborate in message development, and test messages and programs to see if they are working as intended.").

Blaisdell et al., supra note 19, at 483-85.

<sup>199</sup> Sax & Doran, *supra* note 22.

can certainly be neutral and allow consumers to have information. The problem is that consumers make inappropriate associations with various food labels.<sup>200</sup> In one study, survey participants found the GMO label to be less healthy, less safe, and less environmentally friendly compared to a variety of other labels, including the labels "organic" and "natural."<sup>201</sup> Since the label "natural" has no regulatory definition, such a label does not provide information to consumers.<sup>202</sup> But. marketing companies know that consumers have positive associations with the term "natural" and this is seen very prominently in the dietary supplement industry.<sup>203</sup> A recent episode of Keeping Up With the Kardashians showed Kourtney Kardashian food shopping with her son. In this episode, Ms. Kardashian found gum labeled "natural" and seemed very pleased to offer this gum to her son. It would be interesting to know if the ingredients in the gum labeled "natural" differ compared to other commercial gum. Labels appear to matter to consumers, which is completely fine, but the labels should provide information in a way that allows consumers to make informed choices. If consumers want to know that their food is healthy, for example, then labels can respond to that concern. The problem is that the label "natural," for example, does not accurately provide that information, but many consumers think that it does.<sup>204</sup>

In the GMO controversy, understanding consumer preferences can allow policymakers to provide accurate information in a way that responds to the consumer needs. For example, studies could divide subjects into different groups and provide accurate information in a way that responds to consumer preferences. Testing participant responses via survey could be used to analyze whether the information provided led to different responses. Put differently, policymakers need to understand how to communicate with consumers so that the

<sup>204</sup> See, e.g., Andrew Sullivan, *Naturally Nonsense*, THE DISH (June 25, 2014, 5:17 PM), http://dish.andrewsullivan.com/2014/06/25/naturally-nonsense/.

<sup>&</sup>lt;sup>200</sup> Id.

 $<sup>^{201}</sup>$  Id.

<sup>&</sup>lt;sup>202</sup> "Natural" on Food Labeling, FOOD & DRUG ADMIN., http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInf ormation/LabelingNutrition/ucm456090.htm (last updated May 9, 2016) (responding to citizens petitions to try to establish a definition for the term "natural").

<sup>&</sup>lt;sup>203</sup> See Joanna K. Sax, Dietary Supplements are Not all Safe and Not all Food: How the Low Cost of Dietary Supplements Preys on the Consumer, 41 AM. J.L. & MED. 374, 377 (2015) (internal citations omitted) ("Manufacturers exploit this preference in their marketing techniques, by touting their supplement as 'natural.' The perception of some consumers is that anything that is natural is safe. But, of course, that is not true. Many poisonous and dangerous things are natural, such as wild mushrooms. Tobacco is another natural ingredient that is linked to adverse health consequences.").

## SETON HALL LAW REVIEW [Vol. 47:433

consumers can separate the wheat from the chaff. A specific study could include statements by smaller farmers who want to use biotechnology to address a niche problem in their area. Studies show that consumers perceive organic farming as local and small, and like the idea of a return to wholesomeness.<sup>205</sup> Consumers may be surprised to learn biotechnology can be used to solve niche problems, but that it has been kept out of reach of small, local farmers due to the time and expense associated with regulatory review.<sup>206</sup> For consumers who are concerned about sustainable farming, for example, they may be interested to learn that the use of genetic engineering to solve a distinct problem, such as a virus that infects crops in a particular area of the country, is out of reach for some farmers, leading to crop loss. Additional information about health and safety profiles of genetically engineered food may also be illustrative to consumers. By understanding the preferences of consumers, information can be provided in a way that accurately responds to these concerns. Perhaps small farmers who want to use genetically engineered crops can reach the consumers who are attracted to the same attributes that they associate with local organic farming.<sup>207</sup> Put differently, some of the reasons that consumers chose to buy organic are also reasons to buy food made from local farmers who want to use biotechnology to solve a niche problem. Consumers may be unaware of the benefits of food produced from GMOs. If consumers understand the application of biotechnology, they may see the benefit as high and possibly assign a lower probability of risk.

The controversy surrounding the treatment of dairy cows with rbST overlaps with the GMO debates. To date, no scientific consensus exists that treatment of cows with rbST causes health issues in humans. But, consumers who see an "rbST-free" label might relate this label with some sort of negative association, such as a health or safety issue; i.e. with milk from cows treated with rbST. Empirical studies analyzing consumer associations with rbST labels can easily be conducted, in a similar fashion as the GMO labeling study described above. Additional studies can be aimed at providing accurate information regarding

<sup>&</sup>lt;sup>205</sup> Hughner et al., *supra* note 72, at 101–03. See also, for example, a pro-organic company called WHOLESOME!, http://wholesomesweet.com/ (last visited Nov. 23, 2016).

<sup>&</sup>lt;sup>206</sup> See Strauss & Sax, *supra* note 82, at 475 (internal citation omitted) ("This is a major factor preventing most small companies and public sector breeders from using GMO methods.... This recognizes that the current regulations have the practical consequence of keeping innovations out of the marketplace, including more environmentally friendly or healthy alternatives.").

<sup>&</sup>lt;sup>4</sup> Control groups would also be included in any study.

rbST treated cows in an attempt to see if this changes consumer responses to various labels.

Fluoridated water programs are similar to vaccination programs because of the widespread implementation. Adding fluoride to the public water supply makes it very difficult for a consumer to opt out. In addition, the risk of any adverse event from fluoride in the water is very low and the public health benefit is very high.<sup>208</sup> For this reason, it is important to compare whether different methods of communication that provide accurate information change the way consumers make decisions. Whether consumers respond differently can be tested using focus groups or responses to survey questions.

In the debate surrounding embryonic stem cell research, consumers received conflicting and inaccurate information. As discussed earlier, one study showed that mainstream newspapers inaccurately reported that adult stem cells were equal to embryonic stem cells, suggesting that research on embryonic stem cells was not needed.<sup>209</sup> It is unclear if consumers were used as pawns in a political debate, but that is certainly an inference that can be made. In the past fifteen years, scientists have learned much more about stem cells in general. In some cases, adult stem cells do provide a better starting material compared to embryonic stem cells and vice versa.<sup>210</sup> This is important information obtained through many years of research.<sup>211</sup> Scientists do not know the answers until they test their hypotheses. Consumers should be provided with information based on actual data in order to make informed decisions about controversial areas of funding. A longitudinal study analyzing consumer perceptions of embryonic stem cell research over time might provide interesting information to see if perceptions change as more information is obtained.

When consumers do not understand the science, they are more likely to inappropriately assign a high risk to that particular application

<sup>&</sup>lt;sup>208</sup> See generally supra Section II.D.

<sup>&</sup>lt;sup>209</sup> Sax, *The Separation of Politics and Science, supra* note 146, at 17.

<sup>&</sup>lt;sup>210</sup> Stem Cell Basics – What are the similarities and differences between embryonic and adult stem cells?, NAT'L INSTS. OF HEALTH, http://stemcells.nih.gov/info/basics/pages/basics 5.aspx (last updated Mar. 3, 2015) ("Scientists believe that tissues derived from embryonic and adult stem cells may differ in the likelihood of being rejected after transplantation... Adult stem cells, and tissues derived from them, are currently believed less likely to initiate rejection after transplantation.").

<sup>&</sup>lt;sup>211</sup> See, e.g., Stem Cell Basics – What are adult stem cells?, NAT'L INSTS. OF HEALTH, http://stemcells.nih.gov/info/basics/pages/basics4.aspx (last updated June 17, 2015) ("In a variation of transdifferentiation experiments, scientists have recently demonstrated that certain adult cell types can be 'reprogrammed' into other cell types in vivo using a well-controlled process of genetic modification[.]").

# 474 SETON HALL LAW REVIEW [Vol. 47:433

of technology. Consumers should be in a position to make informed decisions. The concern is that with so much conflicting information available, it is challenging for a consumer to know what information to use. Studies are needed to understand the best ways to provide accurate information to consumers to allow them to be in a position to appropriately assign the benefits and risks to a particular decision.<sup>212</sup>

#### B. Theme 2: Scientific Uncertainty is Different than Risk

Second, scientific uncertainty is part of the scientific process. Unknowns always exist in science, but this is different than having enough information to be able to assign a probability of risk. Consumers may have trouble differentiating between scientific uncertainty and risk. The question becomes how to communicate not only the science, but also that some scientific uncertainty still allows consumers to assign a risk. The American Association for the Advancement of Science (AAAS) has dedicated significant efforts to creating interactions between scientists and society.<sup>213</sup> Corporations and other interested actors are also testing and implementing consumer outreach programs.<sup>214</sup> Scientific uncertainty does not mean that policymakers do not have enough information to make informed policy decisions.

A physician may never be able to say that vaccines are 100 percent safe all the time and that no adverse event could ever be related to a vaccine. Some small risks exist. A small risk of infection, for example, might occur at the injection site. This uncertainty however, pales in comparison to the overwhelming amount of evidence regarding the benefits of vaccines. An example of scientific uncertainty might be testing and revisiting the best timing for administration of immunization to allow patients to obtain the highest level of immunity. This type of scientific uncertainty and need for ongoing studies should not be confused with the overwhelming amount of evidence demonstrating the efficacy of vaccines. Consumers may conflate risk and uncertainty in the following way: a parent might believe that because recommended doses and timing of those doses change, the scientific community does not really understand what it is doing, and

<sup>&</sup>lt;sup>212</sup> The author is grateful to a colleague who used the terminology, separating wheat from chaff, to describe an issue (although in another setting). This description spurred the name for this theme.

<sup>&</sup>lt;sup>213</sup> See AAAS, supra note 171.

<sup>&</sup>lt;sup>214</sup> See, e.g., The Conversation, MONSANTO, http://discover.monsanto.com/

conversation/ (last visited May 24, 2016) (providing a forum for consumers to ask questions).

therefore assign a high risk to any vaccination protocol or recommendation. To be fair, the skepticism of scientific uncertainty may be greater in consumers due either to changes in medical advice (for example, fat is not as bad as we once thought for our diets) or larger paradigm shifts. But, as discussed earlier in this article, this must be fairly balanced with overwhelming evidence that scientific advances allow us to live longer and healthier lives compared to our ancestors.

The studies described within this article can provide important insight regarding how consumers make decisions when the risks are unknown. If consumers experience the feeling of dread, they are likely to assign a high risk to the outcome.<sup>215</sup> If consumers feel that the administration of a vaccine to their children will cause major long-term and irreversible problems, they may choose not to vaccinate.<sup>216</sup> Perhaps because scientists and physicians may never be able to say that vaccines are 100 percent safe, parents may experience a negative affect if they think that their children would be part of the very small group that has an adverse reaction. Would consumers feel differently about the assignment of risk of a vaccine if it is placed in the context of other types of risks? The risk of being killed in a driving accident is greater than the risk of an adverse event from a vaccine.<sup>217</sup> Studies can test whether the negative feelings associated with particular decisions can be adjusted by providing information about risk. Would consumers feel differently about the assignment of risk if they understood the difference between scientific uncertainty and risk? Studies are needed to evaluate how to provide this type of information to consumers in such a way.

The scientific consensus for food produced from GMOs is that it is as safe as conventional food.<sup>218</sup> It is possible that in the future some

<sup>&</sup>lt;sup>215</sup> Slovic, *The Affect Heuristic, supra* note 14, at 1342.

Cf. Blaisdell et al., *supra* note 19, at 483–85.

<sup>&</sup>lt;sup>217</sup> Compare General Statistics, INS. INST. FOR HIGHWAY SAFETY, http://www.iihs.org/iihs/topics/t/general-statistics/fatalityfacts/state-by-stateoverview (last visited June 11, 2016) ("There were 29,989 fatal motor vehicle crashes in the United States in 2014 in which 32,675 deaths occurred."), with Aaron

In the United States in 2014 in which 32,075 deaths occurred. ), with Aaron Sharockman, What CDC Statistics Say about Vaccine-Related Illnesses, Injuries and Death, POLITIFACT (Feb. 3, 2015, 3:32 PM), http://www.politifact.com/punditfact/statements /2015/feb/03/bob-sears/what-cdc-statistics-say-about-vaccine-illnesses-in/ (reporting data on vaccine related deaths at 122 for the year 2014, with the VEARS disclaimer that "[w]hen evaluating data from VAERS, it is important to note that for any reported event, no cause-and-effect relationship has been established. Reports of all possible associations between vaccines and adverse events (possible side effects) are filed in VAERS. Therefore, VAERS collects data on any adverse event following vaccination, be it coincidental or truly caused by a vaccine. The report of an adverse event to VAERS is not documentation that a vaccine caused the event").

<sup>&</sup>lt;sup>®</sup> See Press Release, supra note 93.

#### SETON

## SETON HALL LAW REVIEW [Vol. 47:433

type of conventional food or food produced from a GMO might not be safe. This possibility is a scientific uncertainty, but should not be used for risk assignment by consumers. Given the precise nature of genetic engineering technology, a scientist might hypothesize that genetically engineered food has a higher, or at least similar, likelihood of safety compared to food produced from conventional methods.<sup>219</sup> But, in practice, both of these types of food are safe. And, both types of processes—genetic engineering and conventional methods should continue to be subject to scientific scrutiny. Given the many decades of research comparing genetically engineered food to conventional food, the safety risk of genetically engineered food is the same as conventional food.<sup>220</sup>

In the rbST example, scientific studies indicate that humans who consume milk have elevated levels of IGF-1.<sup>221</sup> IGF-1, if unregulated, can contribute to the risk of cancer.<sup>222</sup> These studies also show that the elevated levels of IGF-1 are found regardless of whether the milk is from cows treated with rbST or not.<sup>223</sup> Therefore, there is no evidence suggesting a causal link between milk from rbST treated cows and cancer in humans. Future scientific studies are needed to understand why consumption of milk is associated with higher levels of IGF-1 in humans. This scientific uncertainty is different from risk. In other words, no adverse human health events are associated with rbST and, the risk of developing cancer from drinking milk from cows treated with rbST is similar to drinking milk from cows not treated with rbST. The word "cancer" has been associated with strong affect in decision-Thus, it is likely that by using the word "cancer" or making.<sup>224</sup> insinuating "cancer" in association with milk treated with rbST in advertising, marketing, or internet searches, consumers will

<sup>&</sup>lt;sup>219</sup> *Cf.* Conko et al., *supra* note 78, at 494 ("The essence of these principles is that the mere fact that an organism has been modified by recombinant DNA or other molecular techniques has no bearing on the degree of hazard or level of risk and therefore should not determine whether (or how stringently) the organism is regulated.").

<sup>&</sup>lt;sup>220</sup> See supra Section II.B.

<sup>&</sup>lt;sup>221</sup> AM. CANCER SOC'Y, *supra* note 121; *see also* FDA Report on rBST, *supra* note 110.

See Herbert Yu & Thomas Rohan, *Role of the Insulin-Like Growth Factor Family in Cancer Development and Progression*, 92 J. OF THE NAT'L CANCER INST. 1472, 1472 (2000) ("Functionally, IGF-1 not only stimulates cell proliferation but also inhibits apoptosis. It has now been recognized that the combination of these mitogenic and antiapoptotic effects has a profound impact on tumor growth.").

<sup>&</sup>lt;sup>223</sup> AM. CANCER SOC'Y, *supra* note 121.

<sup>&</sup>lt;sup>224</sup> Slovic, *The Affect Heuristic, supra* note 14, at 1342 ("Thus activities associated with cancer are seen as riskier and more in need of regulation than activities associated with less dreaded forms of illness, injury, and death (e.g. accidents).").

inappropriately assign risk. Empirical studies aimed at providing consumers with the difference between scientific uncertainty and risk may assist consumers with decision-making.

Some of the controversy surrounding fluoridated water relates to using scientific uncertainty to incite fear. Over many decades, scientists continued to research the optimal level of fluoride to add to water. The recommendations have changed over time, with a decrease in the optimal amount.<sup>225</sup> This does not mean that scientists do not understand what they are doing; rather, it means that scientists and public health officials are monitoring and adjusting fluoride levels based on data. The risk, however, of not fluoridating water is greater, especially in poor populations which have less access to regular dental care. Consumers who oppose fluoridation are weighing risks in the wrong direction.

The debate surrounding embryonic stem cell research raises a different concern compared to the other examples. One postulated risk of this type of research could be (or could have been) exploiting women for their eggs.<sup>226</sup> Strict guidelines for egg donation were created.<sup>227</sup> Other risks with the application of therapies derived from stem cell research are similar to the risks associated with clinical trials for any experimental treatment. In addition, Institutional Review Boards have specific guidelines to follow when proposed studies utilize embryonic stem cells.<sup>228</sup> It would be interesting to study whether consumers view clinical trials using treatments derived from embryonic stem cell research as riskier than clinical trials using other experimental procedures. And, if consumers perceive greater risk with

<sup>227</sup> Stem Cell Information, National Institutes of Health Guidelines on Human Stem Cell Research, NAT'L INSTS. OF HEALTH, http://stemcells.nih.gov/policy/pages/2009guide lines.aspx (last updated Apr. 12, 2015).

<sup>&</sup>lt;sup>225</sup> Public Health Service Recommendation for Fluoride Concentration in Drinking Water for Prevention of Dental Caries, 80 Fed. Reg. 24,936 (May 1, 2015), https://www.gpo.gov/fdsys/pkg/FR-2015-05-01/pdf/2015-10201.pdf ("PHS now recommends an optimal fluoride concentration of 0.7 milligrams/liter (mg/L).").

<sup>&</sup>lt;sup>226</sup> See Erica Haimes et al., Eggs, Ethics and Exploitation? Investigating Women's Experiences of an Egg Sharing Scheme, 34 SOC. OF HEALTH & ILLNESS 1199, 1199 (2012) ("In brief, our analysis suggests that while interviewees acknowledge the potential of this scheme to be exploitative, they argue that this is not the case, emphasizing their ability to act autonomously in deciding to volunteer. Nonetheless, these freely made decisions do not necessarily take place under circumstances of their choosing. We discuss the implications of this for egg provision in general and for understandings of exploitation.").

<sup>&</sup>lt;sup>228</sup> Id.; see, e.g., Form for Egg Donation for Human Embryonic Stem Cell Research (Solely for Stem Cell Research), N.Y. DEP'T OF HEALTH, http://stemcell.ny.gov/form-egg-donationhuman-embryonic-stem-cell-research-solely-stem-cell-research (last visited July 4, 2016).

# SETON HALL LAW REVIEW [Vol. 47:433]

treatments from embryonic stem cell research, then it would be valuable to know why that it so. In this way, information can be communicated in order to allow consumers to appropriately assign risk.

In sum, future studies can build on this and incorporate decisionmaking research to test how to provide information in a way that allows consumers to appropriately assign risk, especially in the scientific arena when unknowns exist.

# C. Theme 3: Explore Different Methods of Communication that Consider the Role of Affect and Ambiguity

Third, the role of affect and ambiguity should be specifically considered in studies aimed at effective methods of communication. While this is related to Theme 1 (discussed supra Part III.A), the emphasis of Theme 3 is to address how to create studies to analyze the different marketing forces, especially on the Internet, to understand consumer decision-making. It is certainly not an original idea that marketing impacts consumer decision-making or that industry takes advantage of this. It is important, however, to conduct studies not only to see how a particular industry or interest group utilizes affect and ambiguity to steer consumers *away* from a particular area of biotechnology, but to also test whether different approaches can be used to *combat* a message that creates ambiguity or feelings of "badness." We know, for example, that consumers are more likely to appropriately assign risk if they understand the science. We also know that consumers are less likely to appropriately assign risk when they receive ambiguous information. The question becomes how to communicate the information in a way that recognizes the role of affect and ambiguity.

Various approaches appear to be underway. An entire website highlights stories about how VHPs changed their position once one of their children contracted a vaccine-preventable disease.<sup>229</sup> Recent commentary in this area suggests that VHPs have little ability to weigh the risks because of a lack of personal experience with the consequences and complications associated with these diseases.<sup>230</sup> Thus, the vaccine-preventable diseases, such as polio, measles and

#### 478

<sup>&</sup>lt;sup>229</sup> Tara Hills, *We Learned the Hard Way*, VOICES FOR VACCINES (May 24, 2016), http://www.voicesforvaccines.org/we-learned-the-hard-way/.

<sup>&</sup>lt;sup>230</sup> See, e.g., Emmi S. Herman, *Measles and My Sister*, VOICES FOR VACCINES (May 24, 2016), http://www.voicesforvaccines.org/measles-and-my-sister/ ("[T]oday's parents and physicians are less likely to have had any personal experience with the cruel disease.").

mumps, may not seem real or deadly.<sup>231</sup> But, once a parent sees his/ her child with the disease, the parent might feel differently about the risk of vaccines. Using VHPs who changed their position might seem, intuitively, as a good way to assist parents in assigning risks to vaccinations.<sup>232</sup> A former-VHP might be in a good position to reach a current-VHP in a way that is different than how they might respond to a pharmaceutical company. This type of approach should be empirically tested to see if it has the desired response. Is it, for example, impacting how VHPs make decisions? In other words, do consumers respond differently to different sources that they perceive as credible? Studies aimed at understanding how consumers respond to different sources (and marketing related thereto) may provide insight as how to allow consumers to appropriately assign risk. It is important to compare how consumers respond to anti-vaccine marketing techniques versus experimental pro-vaccine marketing Understanding which techniques and why they are techniques. effective (or ineffective) is important to communicate with consumers (and marketing experts have known this for decades), but this theme aims to suggest studies that utilize affect and ambiguity theories to reach consumers in a way that gives them the ability to appropriately assign risk.

Similarly, with GMOs, the question is: what is the most effective method of communication regarding the application of the technology? Studies aimed at comparing different messengers of the technology—big corporations, publicly funded agriculture scientists, small farmers, organic farmers (who may not oppose genetic engineering technology), mothers, children, or others—could assist with understanding how these communication methods allow consumers to more appropriately assign risk. The experimental conditions should be compared to the current marketing techniques that consumers already experience. Studies aimed at digesting the role of affect and ambiguity, especially if the credibility of sources is at issue, will be important for communication tactics.

The controversy surrounding rbST has many similarities to GMOs. Studies aimed at developing communication tactics that consider affect and ambiguity as part of the decision-making process need to be conducted. If consumers are concerned about animal welfare, then perhaps veterinarians might be a potential messenger to

<sup>&</sup>lt;sup>231</sup> Cf. id.

<sup>&</sup>lt;sup>232</sup> For examples and stories of VHPs who changed their positions, see *Anti-Vax to Pro-Vax*, VOICES FOR VACCINES (May 24, 2016), http://www.voicesforvaccines.org/category/anti-vax-to-pro-vax/.

## SETON HALL LAW REVIEW [Vol. 47:433

provide accurate information regarding animal welfare. If consumers are concerned about adverse human health consequences, scientists and physicians might be good messengers. In these groups of messengers, it would be interesting to compare variables, such as whether the veterinarians, scientists and physicians are from universities versus the private sector, or whether they receive their financial support from the private sector or government grants. By using techniques that allow for testing affect and ambiguity with these different variables (including software aimed at behavioral research studies), it may be possible for policymakers to provide accurate information from trusted sources.

Fluoridated water programs suffer from the same issues described above. Since most consumers are exposed to the public water supply through homes, schools, restaurants, etc., it is important that consumers make informed decisions about this public program. Fear of adverse events associated with fluoridated water impacts decisionmaking. Studies aimed at examining how to provide accurate information to consumers about fluoride are needed. An example of a specific study might be to compare how consumers respond to a widespread campaign of posting factual information using signs about fluoridated water supplies in various public places, including post offices, restaurants, hospitals, and grocery stores. Three sets of signs can be designed: one set that suggests feelings of "goodness," another set that suggests feelings of "badness," and a final set that does not suggest a particular feeling. A fourth group would not see any signs. Follow-up survey questions can compare consumer responses to fluoridated water programs. If groups respond differently, this would suggest that providing (or marketing) accurate information in a way that incorporates affect impacts consumer decision-making.

Despite contemporary advances in medicine, we still currently have many untreatable and highly debilitating diseases, such as Alzheimer's disease. Scientists hope that embryonic stem cell research may open doors to create cures for currently un-curable diseases.<sup>233</sup> Patients and family members are searching for treatments and cures for highly debilitating diseases—often with the patient participating in

480

<sup>&</sup>lt;sup>233</sup> See, e.g., Stem Cell Basics – What are the potential uses of human stem cells and the obstacles that must be overcome before these potential uses will be realized?, NAT'L INSTS. OF HEALTH, http://stemcells.nih.gov/info/basics/pages/basics6.aspx (last updated Mar. 5, 2015) ("In people who suffer from type 1 diabetes, the cells of the pancreas that normally produce insulin are destroyed by the patient's own immune system. New studies indicate that it may be possible to direct the differentiation of human embryonic stem cells in cell culture to form insulin-producing cells that eventually could be used in transplantation therapy for persons with diabetes.").

early clinical trials.<sup>234</sup> It would be interesting to compare communications from patients (and their family members), physicians, and scientists to understand if consumers respond differently. It may also be possible to separate out those that oppose embryonic stem cell research for purely moral reasons versus those that oppose embryonic stem cell research based on reasons related to affect or ambiguity. Focus groups, similar to the study design used by Blaisdell and colleagues, may provide helpful information to identify underlying rationales.

The debates surrounding controversial biotechnology discussed in this article suffer from communication and marketing issues. Consumers are provided with conflicting information, often with emotional undertones, which impacts their ability to assign risk to the application of the underlying technology.<sup>235</sup> Given consumer mistrust of pharmaceutical companies, other tactics are needed to communicate the risks and benefits to consumers.<sup>236</sup> Is it possible for big agricultural and pharmaceutical companies to build (or re-build) the reputational value that other big companies, such as Costco, appear to have with consumers?<sup>237</sup> Would brand-enhancement in these industries even have an impact? Studies can be conducted to compare consumer perceptions of risk based on brand reputation. Or, perhaps, are personal stories (by former VHPs, for example) more effective in allowing consumers to assign risk? Or, are there particular celebrities or other well-known people who could be influential by saying that they, inter alia, vaccinate their children, or eat food from GMOs? Future studies can assess the role of affect and ambiguity by comparing various communications and marketing approaches.

<sup>&</sup>lt;sup>234</sup> See NIH Clinical Research Trials and You, The Basics, NAT'L INSTS. OF HEALTH, https://www.nih.gov/health-information/nih-clinical-research-trials-you/basics (last updated Apr. 29, 2016) ("Participants with an illness or disease also participate to help others, but also to possibly receive the newest treatment and to have the additional care and attention from the clinical trial staff. Clinical trials offer hope for many people and an opportunity to help researchers find better treatments for others in the future.").

<sup>&</sup>lt;sup>235</sup> *Cf.* Johnson, *supra* note 184 ("A study published this month on the Proceedings of the National Academy of Sciences suggested that it is more effective to appeal to anti-vaxxers through their emotions, with stories and pictures of children sick with measles, the mumps or rubella—a reminder that subjective feelings are still trusted over scientific expertise.").

<sup>&</sup>lt;sup>236</sup> See, e.g., Kessel, *supra* note 164, at 988–90.

<sup>&</sup>lt;sup>237</sup> Bryan Pearson, *In Brand We Trust: How Recalls at Trader Joe's, Costco, Can Enhance Customer Engagement,* FORBES (May 18, 2016, 4:33 PM), http://www.forbes.com/sites/bryanpearson/2016/05/18/in-brand-we-trust-how-recalls-at-trader-joes-costco-can-enhance-customer-engagement/#4661c92e77f4 ("Research shows there is an appetite for brand reliability, even if it reveals fallibility.").

SETON HALL LAW REVIEW

[Vol. 47:433

## D. Theme 4: Address the Difference between Values, Affect and Ambiguity in Decision-Making

This theme presents a particular challenge. How should policymakers address conflicting information and differentiate between value-based decisions and decisions impacted by affect and ambiguity? The theory of evolution provides a nice example of this dilemma. Evolution, for example, is probably the most accepted scientific theory ever, yet the public perception is that scientists do not have a consensus.<sup>238</sup> A recent Pew Research survey showed:

While 98% of scientists connected to the American Association for the Advancement of Science say they believe humans evolved over time, only two-thirds (66%) of Americans overall perceive that scientists generally agree about evolution, according to 2014 data from a recent Pew Research Center survey on science and society. Those in the general public who reject evolution are divided on whether there is a scientific consensus on the topic, with 47% saying scientists agree on evolution and 46% saying they do not.<sup>239</sup>

Are consumers receiving conflicting information that leads them to believe that scientists do not agree? If so, it is important to understand where these consumers are receiving their information. Perhaps consumers are receiving information from religious sources that disagree with the scientific consensus.<sup>240</sup> It becomes very difficult to address how to tackle the presentation of conflicting information from trusted sources, especially if individual values are at play. This is a particular challenge for policymakers. Studies aimed at effectively separating the role of affect and ambiguity from value-driven decisions will be important for implementing evidence-based policies.

In the vaccination controversy, it is important to separate whether VHPs are making value-based decisions or risk-based decisions. VHPs may feel strongly about their position; that is, for them, it feels like a value based decision. Or, the role of autonomy, certainly a legal value, may be implicated in a VHP's decision. Studies are needed to dissect the difference between a value-based decision and a risk perception decision. The value of autonomy presents major challenges in

<sup>&</sup>lt;sup>238</sup> See, e.g., David Masci, On Darwin Day, 5 Facts About the Evolution Debate, PEW RES. CTR. (Feb. 12, 2016), http://www.pewresearch.org/fact-tank/2016/02/12/darwinday/.

 $<sup>^{239}</sup>$  Id.

<sup>&</sup>lt;sup>240</sup> *Id.* ("Of all the major religious groups in the U.S., evangelical Protestants are among the most likely to reject evolution. According to the Religious Landscape Study, a solid majority (57%) of evangelicals say humans and other living things have always existed in their present form.").

implementing major public health policies. It is possible, however, to try to understand whether VHPs believe they are making a value-based versus risk-based decision. If it is possible to provide information in a way that allows VHPs to appropriately assign risk to a decision to vaccinate, then it is fair to characterize it as a risk-perception decision. Accurate information can be provided to subjects regarding the risks of vaccinating and non-vaccinating and then follow-on questions can be presented to subjects that are framed as testing values versus risk and comparing the answers.

While some of the resistance to GMOs may be due to an inappropriate assignment of risk, another possibility is a moral/valuebased opposition to changing the DNA. Put differently, a value-based opposition may be that science is interfering with "God's design."<sup>241</sup> This is a particularly interesting value-based opposition because conventional breeding also mutates DNA, albeit with less precision. Once again, it is important to learn whether consumers are making decisions based on values or perceptions of risk. Studies addressing consumer concerns about health, safety and environment of food produced from GMOs compared to understanding value-based decisions will be important to understand the reasons underlying consumer decision-making.

The controversy surrounding rbST does not appear to have the same ethical or value-driven concerns as seen in other examples discussed within this article. However, treatment of cows with rbST certainly could raise these same types of issues because the rbST allows cows to continue to produce milk in an artificial setting. Despite that the public controversy around rbST is not cast in a value-driven dialogue, it would still be interesting to test whether values are at play in consumer decision-making. And, perhaps, a more interesting question is to understand why this type of biotechnology has not suffered from the same values-driven debate as vaccines, GMOs, and embryonic stem cell research. Studies aimed at separating why some forms of biotechnology are heavily value-laden or not may provide powerful insight to address the more controversial examples provided herein.

The controversy surrounding fluoridated water implicates the

<sup>&</sup>lt;sup>241</sup> Jonathan Frochtzwajg, *Playing God? Many Faiths Agree that Tinkering with Genes is Out of Bounds*, THE GENETIC LITERACY PROJECT (May 7, 2015), https://www.geneticliteracyproject.org/2015/05/07/playing-god-many-faiths-agree-that-tinkering-with-genes-is-out-of-bounds/ ("Religious views on GMOs are as varied as religious traditions themselves, but there are some common theological threads. Chief among them: the belief that to change genetic material is to play God.").

# SETON HALL LAW REVIEW [Vol. 47:433]

value of autonomy. Since it is very hard to opt out of exposure to the public water supply, fluoridation programs violate individual autonomy. The value of autonomy is not unlimited. As drivers on the road, we cannot drive wherever we want; instead, we are required to obey traffic rules. Rules that are meant to benefit the public often violate individual autonomy. For fluoridated water programs, scientific data demonstrates that the benefit to the public greatly exceeds any risk. Studies aimed at communicating fluoridated water programs as similar to other public benefit programs may assist to override an objection based on autonomy.

The debate about embryonic stem cell research highlights the issues that arise with addressing the difference between decisions based on values versus decisions that implicate affect and ambiguity. In a previous study analyzing information provided to consumers about federal funding of embryonic stem cell research, articles (including editorials) in mainstream newspapers that suggested adult stem cells could provide that same information as embryonic stem cells was not supported by the scientific evidence at the time.<sup>242</sup> Consumers were asked to weigh-in on the funding of embryonic stem cell research, but they were provided with contradictory information-that is, that adult stem cells could provide similar information as embryonic stem cells, thus avoiding the need to fund a controversial area of research. Values and emotions related thereto were also incorporated in the discussion. This is not to say that consumers cannot be opposed to embryonic stem cell research; rather, a difference exists between a value-based decision and a decision based on ambiguous information. Put differently, a moral opposition is different than a decision based on ambiguity.

# E. The Role of Risk-Perception in Policymaking

Empirically testing ways to provide accurate information in a way that considers consumer decision-making has some complications and limitations. Accurately providing scientific information necessarily means that there is always some degree of uncertainty. Opponents to controversial biotechnology exploit scientific uncertainty. Simply telling consumers that the unknown risks are likely small will not assuage consumers and will not allow them to appropriately assign risk. While factsheets by the Center for Disease Control, Food and Drug Administration and National Institutes of Health are important, they do not necessarily reach the weary and overwhelmed consumer. Since

<sup>&</sup>lt;sup>242</sup> Sax, *The Separation of Politics and Science, supra* note 146, at 7–14.

consumers are wading through both information and misinformation, various tactics have to be employed to allow consumers to make informed choices. These tactics should utilize decision-making research to provide information in a way that allows the consumer to appropriately assign risk.

The above discussion should not be conflated with the issue that scientific exploration should be ongoing. Some uncertainty exists within well-accepted scientific theories—which necessitate additional and ongoing research. But, this should not be confused with how consumers assign risk. For example, an overwhelming amount of data demonstrates that vaccines prevent death and disability from a variety of diseases. This does not mean that research on safety and efficacy of vaccines should end. The scientific community should continue to research, revise, question, and improve vaccines. But, it does mean that we have enough evidence to implement widespread vaccination policies. Thus, while scientific research will continue on vaccines, consumers should appropriately assign a low risk (and high benefit) to standard vaccinations.

In line with ongoing scientific exploration, the policies surrounding the applications of biotechnology should be analyzed and revisited on an ongoing basis. Since scientific uncertainty exists, additional studies will almost always be warranted. Government officials, public health experts, physicians, and scientists must collaborate to analyze issues from the basic sciences to change policies Widespread implementation of policieson an on-going basis. especially as it relates to biotechnology-needs to be accomplished with living documents. Risks must be minimized, but will likely never be eliminated. Put differently, a small risk from a vaccine is still a much smaller risk than not being vaccinated and developing a potentially deadly disease. It is the risk/benefit ratio that needs to govern policies, not whether any risk could exist at any time. Communicating information in a manner that allows consumers to appropriately assign risk is critical to addressing large-scale issues in health, safety, and the environment.

SETON HALL LAW REVIEW

[Vol. 47:433

# CONCLUSION

We have major societal challenges and problems to solve. This article bridges together scientific studies, policy implementation, and decision-making research particularly as to the role of affect and ambiguity in consumer perceptions of risk. Understanding consumer concerns is important to implementing wide-ranging policies, especially in controversial areas such as biotechnology. Given that some degree of scientific uncertainly always exists, it is important for policy makers to communicate information in a way that allows consumers to appropriately assign risk. By combining research from a variety of disciplines, this article articulates common themes that run through each area of consumer concerns. The thematic approach provides general considerations for policy implementation. Within each theme, specific studies are needed that are based on the data and information that we already have about consumer resistance to certain policies. By giving general suggestions of future studies, this article highlights the distinct issues that face each specific area of technology, particularly with respect to consumer concerns and decision-making. This article compares how different studies may assist in understanding how to address consumer decision-making and provides a roadmap for future directions in this area.