STATEMENT OF SUPPORT BY PHYSICIANS and PHYSICIANS ORGANIZATIONS

"PHYSICIANS STATEMENT CALLING ON FDA TO URGENTLY RESPOND TO 2011 CITIZENS PETITION BY CENTER FOR FOOD SAFETY SEEKING FDA REVISION OF CURRENT FDA POLICY REGARDING GENETICALLY ENGINEERED FOODS"

OCTOBER 17, 2014

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PHYSICIANS STATEMENT SUMMARY:

We, the undersigned, as concerned physicians, declare our intent to inform and request the US FDA to urgently respond to a formal citizens petition[i] filed in October 2011 by the Center for Food Safety and 21 supporting organizations and businesses by: 1) advocating thorough, science- based safety testing of GE products prior to marketing; 2) cultivation of GE crops in a manner minimizing risk of contamination of conventional food supplies and the environment ; and 3) providing consumers with a means of identifying GE foods through mandatory product labeling.

BACKGROUND:

- 1958: The Federal Food, Drug and Cosmetic Act (FFDCA) of 1958 grants to the Federal Food and Drug Administration (FDA) the authority to regulate approximately 80% of the US food supply and to be involved in many facets of ensuring the safety of domestic and imported foods.[ii]

- The FFDCA requires pre-market safety testing of any food additive (defined as a substance intentionally added to food), unless a decision is made by FDA, or by consensus among qualified experts outside of government, that the additive is Generally Recognized as Safe (GRAS).[iii]

- GRAS substances do not require pre-market safety testing of any kind although a majority of experts on the FDA's Biotechnology Task Force have concluded that genetically engineered foods pose unusual risks and cannot be presumed safe.[iv]

- Genetic engineering involves gene insertion from one species into an unrelated species, often of a different kingdom, that would not occur without human intervention, and carries the potential to disrupt the genetic code and create unintended changes in gene expression.

- May 26, 1992: The White House Council on Competitiveness called for regulation of Genetically Engineered (GE) food products based on the characteristics of the food itself and not on the production process[v] and further announced that new plant varieties of foods developed through biotechnology will be regulated exactly like conventional foods.[vi]

- May 29, 1992 (3 days later): Consistent with the position of the White House Council on Competitiveness on GE food regulation, the FDA issued a Statement of Policy[vii] stating that

foods derived from new plant varieties, including those developed using recombinant DNA techniques (also known as genetic engineering) will, in most instances, be considered the same or substantially similar to substances commonly found in food.

- FDA's May 29th policy is based on the Agency's assumption (in absence of safety testing or recognized scientific review) that DNA, including recombinant DNA, added to common food substances via genetic engineering is Generally Recognized as Safe (GRAS).[viii] [ix]

- The FDA's May 29th Statement of Policy advises producers of these new plant varieties of food that they may voluntarily consult with FDA on scientific issues[x], and does not require pre-market approval or independent review of safety, with limited exceptions (such as when genes from an organism known to cause human allergies are used in the gene modification process).

- Federal law requires that material facts about food must be disclosed through labeling; however mandatory labeling requirements for genetically engineered foods have not been adopted by FDA. Current FDA policy 1) presumes that genetically altered foods are substantially equivalent to conventional foods; and 2) does not consider genetic engineering to be a material factor differentiating these foods from their conventional counterpart.[xi]

CENTER FOR FOOD SAFETY PETITION: 2011

On October 12, 2011. the Center for Food Safety filed in good faith a formal Citizens Petition in compliance with federal law, contained in 21 CFR Code of Federal Regulations, 10.30, Citizen Petition,[xii] requesting, in conjunction with 21 other concerned organizations and businesses, to request mandatory safety testing and labeling of genetically engineered foods.

The major basis of the Center for Food Safety petition is **"Genetic engineering makes silent but fundamental changes to our food at the molecular level, the full human health and environmental consequences of which are still being discovered. Unlabeled genetically engineered foods are misleading to consumers who, in the absence of labeling, overwhelmingly purchase based on the reasonable assumption that their food is produced conventionally**. **Mandatory labeling for GE foods is necessary in order to prevent consumer deception and economic fraud."**

Organizations signing the 2011 CFS petition include the following:

1) Amy's Kitchen, Petaluma, CA
2) Annie's Homegrown, Berkeley, CA
3) Beyond Pesticides, Washington, DC
4) Center for Environmental Health, Oakland, CA
5) Consumer Reports, Yonkers, New York
6) CROPP, Cooperative (Organic Valley, LaFarge, WI

7) Environmental Working Group, Washington, DC
8) Food and Water Watch, Washington, DC
9) Horizon Organic, Broomfield, CO
10) The Midwest Organic and Sustainable Education Service (MOSES), Spring Valley, WI
11) The National Cooperative Grocers Association (NCGA), Iowa City, IA
12) The National Family Farm Coalition, (NFFC), Washington, DC
13) Northwest Organic Dairy Producers Alliance (NODPA), Deerfield, MA
14) The Northeast Organic Farming Association, Stevenson, CT
15) The National Organic Coalition (NOC)
16) The Organic Seed Alliance (OSA), Port Townsend, WA
17) The Organic Seed Growers and Trade Association (OSGATA, Montrose, CO
18) Organically Grown Company (OGC, Eugene, OR
19) The Rural Development Foundation International (RAFI) – USA.
20) Save New Mexico Seeds, New Mexico
21) Stonyfield Farm, Londonderry, NH
22) Center For Food Safety, Washington, DC (lead petitioner)

Although 21 CFR Code of Federal Regulations required response by the FDA within a maximum of 180 days, no response from FDA has yet been received in spite of lapse of a three year period.

PROPOSED PHYSICIAN STATEMENT:

- **We, the undersigned, as concerned physicians, declare our intention to formally request the U.S. Food and Drug Administration (FDA) to immediately respond to the Center For Food Safety Petition requesting the following: 1) requiring that genetically engineered foods be thoroughly studied and safety tested by independent, accredited research bodies prior to release on the market; 2) requiring cultivation of GE crops in a manner minimizing risk of contamination of conventional food supplies and the environment; and 3) requiring and enforcing mandatory labeling of all genetically engineered food products.**

- **We, as healthcare providers, are concerned about escalating incidence of disease among our patients, and particularly among children, including digestive illness; immune and neurocognitive dysfunction; reproductive disorders and other health concerns paralleling the time period in which genetically engineered foods and associated pesticides have proliferated in the marketplace since 1994.[xiii]**

- **We have serious concerns, based on considerable scientific evidence,[xiv] that genetically engineered foods and their associated pesticides have not been independently studied, tested, nor proven to be safe prior to introduction into the domestic food supply. We strongly believe that these genetically altered foods should not be considered by FDA to be safe.[xv]** [xvi]

Note to Signers of the above Physician Statement: Please go to http://www.labelgmos.org to sign above statement.

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[i] "Citizens Petition Before the United States Food and Drug Administration, October 12, 2011, Petition Seeking Mandatory Labeling of GE Foods, Center for Food Safety, http://www.regulations.gov/#!documentDetail;D=FDA-2011-P-0723-0001

[ii] Public Health Focus: FDA, USDA, NOAA Statements on Food Safety, 3/23/2011, http://www.fda.gov/newsevents/publichealthfocus/ucm248257.htm

[iii] How U.S. FDA's GRAS Notification Process Works, December 2005/January 2006, US Food and Drug Administration, http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/ucm083022.htm

[iv] Alliance for Bio-Integrity, Letter dated 10/23/91, from James H. Maryanski, Ph.D., Biotechnology Coordinator, Center for Food Safety and Applied Nutrition (FDA); Page 1: http://biointegrity.org/FDAdocs/06/view1.html and Page 2: http://biointegrity.org/FDAdocs/06/view2.html For additional letters from FDA Scientists expressing safety concerns, see http://www.biointegrity.org/list.htm

[v] Cimons, Marlene and Walters, Donna K. H., "Stage Set for 'Biotech" Debut at Grocery Store: U.S. Policy to be unveiled today regulates foods created by genetic engineering like other varieties," Los Angeles Times, May 26, 1992. http://articles.latimes.com/print/1992-05-26/news/mn-144_1_genetic-engineering

[vi] Caplan, Richard and Spitzer, Skip, "Regulation of Genetically Engineered Crops and Foods in the United States," US Public Interest Research Group and Pesticide Action Network North America, March 2001, https://nativeseeds.org/pdf/GERegulations.pdf

[vii] FDA Statement of Policy: Foods Derived from New Plant Varieties, Federal Register Vol. 57-1992, 5/29/92 http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/biotechnology/ucm096095.htm

[viii] Overview of FDA Consultations, U.S. Food and Drug Administration, Specialty Crop Regulatory Assistance Workshop, 12/6-12/8, 2011, http://www.specialtycropassistance.org/uploads/ckeditor/files/SCRA%202011%20Workshop%20Presentations/SCRA2011%20FDA%20Overview%20Merker.pdf

[ix] FDA Statement of Policy: Foods Derived from New Plant Varieties, 5/29/92, Federal Register Vol. 7, No. 104 at 22991 http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/biotechnology/ucm096095.htm

[x] Ibid, FDA Statement of Policy: Foods Derived from New Plant Varieties, 5/29/92, Section II, Responsibility for Food Safety (second paragraph of this section).

[xi] "May 26, 1992: FDA Rules that Genetically Modified Food Is 'Substantially Equivalent' to Conventionally Grown Food," Creative Commons, http://www.historycommons.org/context.jsp?item=FDAScResponseTo526Ruling

[xii] CFR, Code of Federal Regulations, Title 21, 10.30, Citizen Petition.

[xiii] Ibid. http://www.beyondpesticides.org/gmos/HerbicideTolerance.php

[xiv] American Academy of Environmental Medicine (AAEM Press Release, May 19, 2009), http://www.aaemonline.org/gmopressrelease.html

[xv] "Statement: No Scientific Consensus on GMO Safety," European Network of Scientists for Social and Environmental Responsibility, October, 2013, See: http://www.ensser.org/increasing-public-information/no-scientific-consensus-on-gmo-safety/

[xvi] "Genetically Modified Foods Position Paper: The American Academy of Environmental Medicine," containing a statement by World Health Organization citing "…several animal studies indicate serious health risks associated with GM food consumption including infertility, immune dysregulation, accelerated aging, dysregulation of genes associated with cholesterol synthesis, insulin regulation, cell signaling, and protein formation and changes in liver, kidney, spleen and gastrointestinal system." (See: http://www.aaemonline.org/gmopost.html)