



Congress Passes FDA Food Safety Modernization Act (FSMA)

by Pete Kennedy, Esq. - December 29, 2010

On December 21, the U.S. House of Representatives passed H.R. 2751, the “FDA Food Safety Modernization Act” (formerly S.510). On Sunday night, December 19, the Senate passed FSMA by unanimous consent without a recorded vote after substituting its language in H.R. 2751 (originally titled, “Consumer Assistance to Recycle and Save Act”—one of the “Cash for Clunkers” bills originating in the House in 2009). This maneuver, cynical and underhanded even by Washington standards, could have been stopped by a single Senate Republican but all were silent. FSMA is expected to be signed into law by President Obama sometime next week.

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Passage of FSMA gives a significant increase in power to the Food and Drug Administration (FDA). FDA will now have mandatory recall power; the agency’s treatment of farmstead cheese operations, Estrella Family Creamery and Morningland Dairy, shows the potential damage the agency can do with mandatory recall to those that have injured no one with their products. FSMA also will lower the standard for the administrative detention of food. Currently, an agency official can’t detain an article of food unless the official has “credible evidence or information that such article presents a threat of serious adverse

health consequences or death to humans or animals.” Under FSMA the official only needs “reason to believe that such article is adulterated or misbranded.”

FDA’s long-term goal is to make the sale of raw milk illegal. The way FDA intends to do this—as stated in the document “Healthy People 2020” [1] as well as “Resolution 10” [2] from the 2005 National Conference on Interstate Milk Shipments (NCIMS)]—is to pressure the States one at a time to change their laws to make the sale of raw milk illegal. FSMA gives FDA more leverage over the States through the agency’s increased jurisdiction over intrastate commerce.

The Tester amendment which exempts from FSMA’s burdensome food safety plan requirement and national produce safety standards those producers selling either processed food or fruits and vegetables with under a half million dollars in gross annual sales who generate more than one half of their sales from direct transactions with either consumers, restaurants, and retail stores. To qualify for the exemption, those producers must either show they are implementing a modified food safety plan or provide documentation showing that the facility is “in compliance with state, local, county or other applicable non-Federal food safety law.” FSMA provides that the exemption is withdrawn if an active investigation links the “qualified facility” to an outbreak of foodborne illness or “if the Secretary determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a qualified facility that are material to the safety of the food manufactured, processed, packed or held at such facility.”

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The exemption will help some, but not all, raw milk producers. Many raw milk producers generate much more income from sales of raw milk to a cooperative for pasteurization than they do from the sale of retail raw milk to consumers. Those producers would not benefit from the exemption. The Tester amendment aside, FSMA is giving more power to an agency that views raw milk as a high priority enforcement item. The bill sets a goal to

increase FDA staff from 4,000 in fiscal year 2011 to 5,000 in fiscal year 2014 [section 401. Funding for Food Safety]. Further, under the new law FDA will be given power to hire state officials to enforce the requirements of FSMA.

The next battle will be the appropriations process in the next session of Congress which will determine how much funding the FDA will get to enforce the requirements of FSMA. Forty years ago, former FDA Commissioner Herbert Ley said of the agency shortly after he left it, “The thing that bugs me the most is that people think the FDA is protecting them - it isn’t. What the FDA is doing and what the public thinks it is doing are as different as day and night.”[3]

Hopefully, the new Congress will pay attention to the agency’s long track record of doing the bidding of the pharmaceutical and biotechnology industries at the expense of public health; and will limit the agency’s funding to enforce the mandates of FSMA to the greatest extent possible. There should be no other result for an agency that has publicly stated that the American people have no “fundamental right to their own bodily and physical health” and “do not have a fundamental right to obtain any food they wish”.[4]

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REFERENCES & NOTES

1. “Healthy People 2020 Public Meetings: 2009 Draft Objectives”; see page 75, objective FS HP2020-9. Accessed at <http://www.healthypeople.gov/2010/hp2020/Objectives/files/Draft2009Objectives.pdf>

Also stated in presentation by CDR Suzan Gordon and Elisa L. Elliot, Ph.D., U.S. Food and Drug Administration, Center for Food Safety and Nutrition, “Healthy People 2010 and 2020: Objectives in Food Safety”. March 2010 in Atlanta; accessed at www.fsis.usda.gov/PDF/Atlanta2010/Slides_FSEC_SGordon.pdf

See slides 39 and 40 for statement, “Increase the number of states that prohibit sale or distribution of unpasteurized dairy products.”

2. “2005 NCIMS Resolution 10”, considered by the National Conference on Interstate Milk Shipments that convenes every two years (also responsible for the PMO, Pasteurized Milk Ordinance, adopted by many States). Incorporated as a PowerPoint slide and posted on FDA’s website at <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/MilkSafety/ConsumerInformationAboutMilkSafety/ucm183140.htm>



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"Therefore, Be It Resolved:

That the NCIMS, due to the serious public health concerns, discourages the consumption of raw milk and encourages states to pass laws or adopt administrative rules that prohibit the sale of raw milk directly to the household consumer and to the unlawful manufacturers of unlawful dairy products;"

"Be It Further Resolved:

That the NCIMS continues to support the motto of the conference, which is "To assure the safest possible milk supply for all the people"."

3. Daniel Haley, *Politics in Healing: Suppression and Manipulation in American Medicine*.

Washington, D.C.: Potomac Valley Press, 2000; pp. 406-407.

4. Pete Kennedy, "[FDA's Response to FTCLDF Suit over Interstate Raw Milk Ban](http://www.farmtoconsumer.org/litigation-FDA-status.htm)", May 6, 2010. <http://www.farmtoconsumer.org/litigation-FDA-status.htm>

This article was originally written by Pete Kennedy for the January 2011 edition of [Graze Magazine](http://www.grazeonline.com) under the title, "FDA Food Safety Modernization Act (FSMA) Passed into Law", and has been edited for posting by the Farm-to-Consumer Legal Defense Fund. Those interested in learning more about Graze may go to www.grazeonline.com or call 608-455-3311. Reprinted by permission.

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HYPERLINKS for PDF version:

S.510 – Litigation page, FDA Food Safety Modernization Act =

http://www.farmtoconsumer.org/federal/111_Cong-S510.htm

H.R. 2751 – Thomas.gov listing of H.R. 2751 bill versions in PDFs and HTML formats =

<http://www.thomas.gov/cgi-bin/query/z?c111:H.R.2751>:

Estrella Family Creamery and Morningland Dairy – Action alert, "Cheesemakers Under Attack" =

<http://www.ftcldf.org/aa/aa-9november2010.htm>

Healthy People 2020 =

http://www.ftcldf.org/docs/health2020-atlanta2010_slides_fsec_sgordon.pdf

Resolution 10 =

http://www.ftcldf.org/docs/ncims2005_resolution_10.pdf

Tester amendment – News, "Analysis of Tester-Hagan Amendment" =

<http://www.ftcldf.org/news/news-3december2010.htm#6>

Healthy People 2020 Public Meetings: 2009 Draft Objectives =

<http://www.healthypeople.gov/2010/hp2020/Objectives/files/Draft2009Objectives.pdf>

2005 NCIMS Resolution 10 =

<http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/MilkSafety/ConsumerInformationAboutMilkSafety/ucm183140.htm>

FDA's Response to FTCLDF Suit over Interstate Raw Milk Ban =

<http://www.farmtoconsumer.org/litigation-FDA-status.htm>

Graze Magazine – webpage, "some dairy articles from past issues" =

<http://www.grazeonline.com/dairy.html>

www.grazeonline.com – website for *Graze Magazine*