

Law and the Public's Health

This installment of *Law and the Public's Health* examines the raw milk controversy and the implications of two federal court decisions for both U.S. Food and Drug Administration enforcement efforts and the ongoing role of state public health agencies in assuring the safety of intrastate consumption of raw milk.

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RAW MILK IN COURT: IMPLICATIONS FOR PUBLIC HEALTH POLICY AND PRACTICE

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Although only about 3% of the U.S. population drinks raw—or unpasteurized—milk, in recent years, the raw milk movement has erupted into an impassioned and increasingly public debate between public health authorities and consumers.¹ In 2012, even as a raw milk outbreak in Pennsylvania sickened 80 people in four states and a new Centers for Disease Control and Prevention (CDC) study reaffirmed the link between foodborne illness risks and raw milk consumption, several states considered legislation that would legalize raw milk sales within their borders, and two federal court decisions involving the regulation and sale of raw milk—*U.S. v. Algyer*² and *Farm-to-Consumer Legal Defense Fund (FTCLDF) v. Sebelius*³—added fodder to the arguments on both sides.

This installment of *Law and the Public's Health* examines the debate regarding raw milk regulation and sales in the United States and the implications of *U.S. v. Algyer* and *FTCLDF v. Sebelius* for public health practice and policy.

BACKGROUND

The past several years have witnessed an increased consumer demand for “whole,” locally grown and produced foods, particularly produce, meat, and dairy. Commensurate with this increase, heated debate has evolved regarding the sale of raw milk between a growing number of consumers on the one side, and state and federal food safety and public health officials on the other. Although the U.S. Food and Drug Administration (FDA) regulations prohibit the interstate sale

of unpasteurized milk for human consumption, 30 states allow raw milk sales within their borders with varying restrictions.

Public health authorities have long noted the significant risk of serious foodborne illness associated with raw milk.⁴ To protect against this risk, the vast majority of dairy products consumed in the U.S. today are pasteurized, a technique in which the milk is heated rapidly to a temperature high enough to kill most foodborne pathogens. Raw milk is not subject to this heating process and, therefore, is more likely to harbor harmful pathogens such as *Campylobacter*, *Salmonella*, *Escherichia coli* O157:H7, and *Listeria*, all of which would have been killed during pasteurization.⁵

Despite the reportedly small number of consumers who drink raw milk, most outbreaks among both pasteurized and unpasteurized milk are attributed to raw milk. In a recent CDC study, researchers found that, of the 56 fluid-milk reported outbreaks between 1993 and 2006, 46 (82%) involved raw milk, while only 10 were attributed to pasteurized milk. These 46 outbreaks led to 930 reported illnesses and 71 reported hospitalizations, with a disproportionate impact on people younger than 20 years of age.⁶

Notwithstanding the known risks of foodborne illness associated with consuming raw milk, the demand for raw milk appears to be increasing. While better taste is often cited as the primary reason consumers choose to drink raw milk, many proponents also believe that the pasteurization process depletes the milk of important properties that otherwise would confer health benefits, such as a reduction in asthma and allergies and improved infection-fighting capabilities.⁷ Although public health authorities stress there is a lack of evidence to back these health-related assertions, state legislators, responding to constituent demand, have introduced a number of bills to legalize the sale of raw milk within their jurisdictions.

REGULATION OF RAW MILK

Federal regulation

FDA authority for regulating the interstate sale of raw milk is found in the commerce clause of the U.S. Constitution, which, in turn, gives Congress the authority to enact legislation affecting interstate commerce, including laws regulating food, drugs, and cosmetics under the Public Health Service Act (PHSA)⁸ and the Food, Drug, and Cosmetic Act (FDCA).⁹ The PHSA authorizes the FDA to adopt and enforce regulations that are necessary, in the agency's view, to prevent the introduction, transmission, or spread of communicable diseases—such as those caused by foodborne pathogens—from one state to another.⁸ Pursuant to this authority, the FDA regulates the sale of milk in interstate commerce according to rules prescribed in its unpasteurized milk regulation, which provides that “no person shall cause to be delivered into interstate commerce or shall sell, otherwise distribute, or hold for sale or other distribution after shipment in interstate commerce any milk or milk product in final package form for direct human consumption unless the product has been pasteurized. . . .”¹⁰

The FDA's authority with regard to raw milk is also found in the FDCA, which gives the FDA responsibility for protecting the public's health by ensuring that food entering interstate commerce is not adulterated or misbranded.¹¹ Raw milk harboring foodborne pathogens would be considered adulterated under the FDCA. But more often, raw milk is the subject of misbranding claims, because bottles of raw milk transported in interstate commerce do not conform to the FDA's “standard of identity” for milk, which requires that any beverage in final packaged form that is labeled as “milk” and sold in interstate commerce be pasteurized.¹²

The federal government's authority to regulate products such as raw milk in interstate commerce is broad and may extend to purely intrastate activities when necessary to make a regulation of interstate commerce effective.¹³ Indeed, as a federal judge found in *Public Citizen v. Heckler*, “should it appear that the interstate sale of raw milk continues, it is within [the U.S. Department of Health and Human Services'] authority at that time to institute an intrastate ban as well . . . [if] . . . necessary to effectuate the interstate ban.”¹⁴ Moreover, in *Gonzales v. Raich*, which involved a federal ban under the federal Controlled Substances Act on locally grown and consumed marijuana, the U.S. Supreme Court held that actual movement of a regulated product into interstate commerce is not a necessary condition for federal intervention.¹⁵ Rather, as Justice Scalia offered in his concurrence, federal laws

can reach purely intrastate practices if such regulation is considered “necessary and proper” to a broader regulatory scheme affecting commerce.¹⁵

State regulation

Although the FDA prohibits the sale of raw milk across state lines, states retain authority through their police powers to regulate the sale of raw milk within their borders. Currently, 20 states and the District of Columbia prohibit the sale of raw milk, while the remaining 30 states allow sales of raw milk; state regulations vary widely.¹⁶ Thirteen states permit sales only on the farm where the milk is produced, while 12 states permit sales of raw milk in retail stores separate from the farm. Five states maintain regulations that allow a combination approach, such as restricting sales to farmers' markets or to “owners” of the cow through “share” agreements.¹⁶

RECENT LITIGATION

With the growing demand for raw milk, consumers in states where such sales are prohibited often seek out other ways to obtain the milk. One approach is in-person purchases from out-of-state farms where raw milk is sold legally; another is entering into cow “shares” or private “buyers' clubs” in which groups of individuals buy or lease partial ownership of a cow and the milk it produces to avoid any interstate transaction involving raw milk. Two recent federal cases examined the legality of these practices under the FDA's unpasteurized milk regulation and the FDCA.

FTCLDF v. Sebelius

In 2010, the FTCLDF brought an action against the FDA challenging the constitutionality of its prohibition on interstate sales of raw milk.³ Plaintiffs included individuals who sought to purchase raw milk in a state where sales were legal and transport it back to their home states—which did not permit such sales—for personal or family consumption. They also included an “agent” for a raw milk buyers' club who obtained raw milk legally from one state and delivered it to club members for personal or family consumption in states that prohibit sales, as well as a farmer who produced raw milk in a state where sales were permitted but knowingly sold to its customers who came into the state to make their purchase but resided in states that prohibit sales.

In the course of the litigation, the federal judge sought information from the FDA regarding the extent to which its unpasteurized milk regulation prohibited the types of sales in which plaintiffs were engaged. In its responses, the FDA generally asserted that all three

types of sales would violate its unpasteurized milk regulation by “causing milk to be delivered into interstate commerce.” The agency further asserted that producers and buyers’ agents who sell, ship, or transport raw milk to consumers in other states, or who solicit interstate sales, would be subject to FDA enforcement actions.³ Notably, however, the FDA indicated to both the court and in separate public communications that it has “never taken, nor does it intend to take, enforcement action against an individual who purchased and transported raw milk across state lines solely for his or her own personal consumption.”¹⁷ In March 2012, the judge dismissed the case against all plaintiffs for lack of standing on the grounds that none of them had actually been the subject of an FDA enforcement action under the unpasteurized milk regulation.³

U.S. v. Allgyer

In February 2012, the FDA emerged the victor in a suit against Daniel Allgyer, a dairy farmer in Pennsylvania. Allgyer had been shipping unpasteurized milk to buyers in Maryland, first through direct-to-consumer sales and later through a cow-share arrangement.² While raw milk sales are legal in Pennsylvania, they are prohibited in Maryland. The FDA filed suit against Allgyer, alleging that he had violated the PHSA, the FDA’s unpasteurized milk regulation, and the FDCA. The agency sought an order from the court that he discontinue all interstate sales of raw milk.

The judge found that Allgyer’s interstate sales of raw milk had violated both the PHSA and the unpasteurized milk regulation by “engaging in conduct that endangers the public health and safety by distributing in interstate commerce unpasteurized milk and milk products in final package form for human consumption.” The court concluded that Allgyer’s cow-share arrangement with his buyers was simply a sham method for continuing his interstate sales. The court further found that, because bottles containing raw milk that were delivered from Allgyer’s Pennsylvania farm to consumers in Maryland were not labeled, the milk was misbranded within the meaning of the FDCA. As a result, the judge issued a permanent injunction prohibiting Allgyer from continuing to sell his raw milk products across state lines.

IMPLICATIONS FOR PUBLIC HEALTH POLICY AND PRACTICE

U.S. Supreme Court precedent grants the federal government broad powers to regulate both goods in commerce and wholly intrastate conduct that nonetheless has a substantial effect on commerce. With increasing interest in raw milk and the willingness of consumers to

travel to neighboring states to obtain it, *U.S. v. Allgyer* and *FCLDF v. Sebelius* both provide an express legal basis for the FDA’s actions while simultaneously offering greater clarity regarding the agency’s enforcement intentions. Consumers living in states where raw milk sales are prohibited can continue to travel to other states where it is sold legally, and transport it back to their home states for personal and family consumption without fear of receiving a warning or worse from the FDA. At the same time, sellers of raw milk products cannot engage in practices that place their products in interstate commerce.

These cases do not in any way undermine the power of state public health agencies to regulate the sale of raw milk within their borders and suggest the importance of continuing efforts by state public health authorities to oversee the consumption of raw milk and educate residents about the associated foodborne illness risks, particularly in children, the elderly, and those with compromised immune systems. State public health agencies play a continuing and crucial role in monitoring raw milk production, responding to foodborne illness outbreaks, and educating state lawmakers regarding the health risks—to residents of their own states as well as other states—associated with raw milk consumption and laws that permit its sale.

At the same time, however, the *U.S. v. Allgyer* decision suggests that producers and buyers’ agents will continue to be the focus of FDA investigations and enforcement actions aimed at curbing the interstate sale of raw milk. In this context, consumers who travel to other states to buy raw milk that is to be subsequently transported back to their own states may provide the evidence on which such enforcement actions will be based under federal law. This bifurcated policy approach—permitting purely local consumption of raw milk in states that allow it while regulating its interstate movement—represents a more tolerant approach than that taken by the federal government in the case of medical marijuana, balancing the authority of states to allow such practices within their borders with the role of the federal government in protecting the nation against unsafe commercial practices.

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REFERENCES

1. Centers for Disease Control and Prevention (US). Foodborne Active Surveillance Network (FoodNet) population survey atlas of exposures. Atlanta: CDC; 2006–2007. Also available from: URL: http://www.cdc.gov/foodnet/surveys/FoodNetExposureAtlas0607_508.pdf [cited 2012 Jul 31].
2. *U.S. v. Allgyer*, 2012 U.S. Dist. LEXIS 13257 (E.D. Pa., Feb. 2012).
3. *Farm-to-Consumer Legal Defense Fund v. Sebelius*, No. C 10-4018-MWB (N.D. Iowa, March 30, 2012).
4. Weisbecker A. A legal history of raw milk in the United States. *J Environ Health* 2007;69:62-3.
5. Food and Drug Administration (US). The dangers of raw milk: unpasteurized milk can pose a serious health risk [cited 2012 May 18]. Available from: URL: <http://www.fda.gov/Food/ResourcesForYou/consumers/ucm079516.htm>
6. Langer AJ, Ayers T, Grass J, Lynch M, Angulo FJ, Mahon BE. Nonpasteurized dairy products, disease outbreaks, and state laws—United States, 1993–2006. *Emerg Infect Dis* 2012;18:385-91.
7. Mendelson A. “In bacteria land”: the battle over raw milk. *Gastro-nomica* (Berkeley Calif) 2011;11:35-43.
8. 42 U.S.C. §264(a).
9. U.S. Constitution. Art. 1, §8, cl. 3.
10. 21 C.F.R. Part 1240.61.
11. 21 U.S.C. §331(a).
12. 21 C.F.R. §131.110(a).
13. *Gonzales v. Raich*, 545 U.S. 1 (2005).
14. *Public Citizen v. Heckler*, 653 F. Supp. 1229 (D.D.C. 1986).
15. *Gonzales v. Raich*, 545 U.S. 1 (2005) (Scalia concurring).
16. National Association of State Departments of Agriculture. NASDA releases raw milk survey [press release]; 2011 Jul 19 [cited 2012 May 18]. Available from: URL: <http://www.nasda.org/cms/32211.aspx>
17. Food and Drug Administration (US). Food safety and raw milk. November 1, 2011 [cited 2012 May 18]. Available from: URL: <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/MilkSafety/ucm277854.htm>