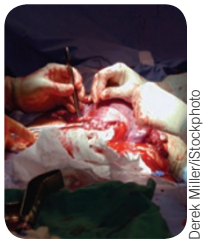
IN brief

Recombinant thrombin approved



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The first recombinant thrombin on the market will be used to control bleeding during surgery.

Four years ago, protein drug developer Zymogenetics in Seattle began developing a recombinant version of the blood-clotting protein thrombin. On 17 January, it received US marketing approval for Recothrom, and a broad label for its use to control bleeding during surgery. Recothrom is the first recombinant thrombin and will compete with a bovine thrombin product sold by Bristol, Tennessee–based King Pharmaceuticals, the market leader, and a human plasma-derived thrombin, Evithrom, from Omrix Pharmaceuticals in New York. (Evithrom was approved in 2007 and is being sold by Johnson & Johnson, of New Brunswick, New Jersey.) Zymogenetics decided to enter the thrombin market after watching King increase pricing and grow its Thrombin-JMI franchise to well above $200 million annually, even with a 'black box' warning for potential immunogenicity. It has reason to think its product could compete because "at the end of the day, there isn't a single example where a recombinant protein fails to take the market over something from plasma or tissue," notes Zymogenetics CEO Bruce Carter. Nonetheless, Wall Street's reaction to the approval was swift and negative: Zymogenetics' stock fell $2 on approval. "We are mystified that there isn't more enthusiasm in the investor community," says Carter. Analyst skepticism is twofold: King has apparently begun discounting the price of Thrombin-JMI to try to keep its market share, and Wall Street fears that Johnson & Johnson hasn't made its best moves yet in promoting Evithrom. All three products appear effective. "Thrombin stops bleeding, whether it's in a cow or a person," notes Piper Jaffray analyst Edward Tenthoff, in New York, and "there isn't a meaningful difference in time to hemostasis" among the three products. With respect to the benefits of a recombinant product, he adds that "in a litigious environment, some will say safety for an increased price is worth it." Tenthoff says Recothrom will eventually succeed and that the market for thrombin will grow: according to Zymogenetics, there are currently 1.3 million US thrombin procedures, 3.5 million topical hemostat procedures and over 11 million potential procedures annually where thrombin may be used. *MR*

In brief *written by Susan Aldridge, Brady Huggett, KS Jayaraman, Lisa Melton, Mark Ratner & Nayanah Siva*

vowed to pass legislation requiring labels for foods from cloned animals and their progeny. In Europe, the European Group on Ethics is asking for a system to ensure "traceability" of locally produced or imported cloned animals.

FDA and EFSA officials put forth nearly identical statements as to the safety for humans of milk and meat products from cloned species such as cattle and pigs, and neither one favors special labeling. Because such foods are "no different" from foods from noncloned animals and there is "no material difference" between cloned or other comparable organisms, the agency does not recommend labeling of such foods, explains Stephen F. Sundlof, director of the FDA Center for Food Safety and Applied Nutrition.

Senator Barbara A. Mikulski has accused the FDA of acting "recklessly" when it issued its risk assessment.

But Mikulski is urging colleagues to pass the Cloned Food Labeling Act (S. 414), and Democratic representative Rosa DeLauro of Connecticut recently introduced a companion bill in the House. The legislation seeks to mandate a simple but all-encompassing label: "This product is from a cloned animal or its progeny."

The bill does not suggest an enforcement mechanism because Mikulski "is hoping that FDA and USDA have enough control over their products to make labeling an asset," says a spokeswoman for the Senator. Inaccurate labeling would face public disapproval, "no different from a company that would lie about calories or fat content." With give and take from both sides, there might be a way to avoid an impasse: Trans Ova and ViaGen last year began to develop on a voluntary basis a supply-chain management program—specifically, a national registry that relies on ear tags to track animals—as a means for identifying and subsequently labeling food products from animals produced through cloning.

Jeffrey L Fox *Washington, DC*

Box 1 Rest of world moving forward

Other countries, including Brazil and Argentina in South America, South Pacific Rim nations such as Australia and New Zealand, and countries in Asia such as China and Japan appear to be on marginally faster tracks toward accepting cloned animals into food production, according to Barbara Glenn, who is managing director of animal biotechnology at the Washington-based Biotechnology Industry Organization (BIO). For instance, although Japanese officials have not made their risk assessment public, they have consulted often and closely with the FDA. "China has a very active interest in building a better beef herd," she says, adding that it "deems itself a leader [in the field], as does Korea."

Separately, the New Zealand Food Safety Authority Food Standards states that "there is no accepted scientific evidence to suggest that food from cloned animals is any less safe than food from non-cloned animals." Australian authorities have adopted that same position. However, only small numbers of animals are cloned in those two countries, and they are "confined to the research environment" for now, authorities say. Meanwhile, Cyagara of Elizabethtown, Pennsylvania, one of three US companies involved in cloning farm animals, offers cattle cloning services through its Goyaike branch in Argentina, whereas the Goyaike branch in Brazil boasts of being the first American institution to clone a sheep.

Though there is progress, it's probable that the rest of the world will wait for the US to serve as a test market, as Europe seems unlikely to take the lead, given its history with genetically modified crops. *JF*

IN their words

"Only a company intent on ignoring the obvious could have missed the evidence of fraud in the study,"

Bart Stupak, chair of the House Energy & Commerce Committee's subcommittee on oversight and investigations, commenting on Sanofi-Aventis' submission to FDA of fake safety data on its Ketek antibiotic.

"Let me state this in no uncertain terms. China is not ready to be a chemical manufacturing hub for the United States and the rest of the world. There's far too great a safety danger. We're getting too many safety signals in recent months. This isn't a catastrophe waiting to happen. This is a catastrophe that is happening."

Michael Santoro, associate professor of business ethics at Rutgers Business School on contaminated heparin manufactured in China.