



Nigerian population, adds information to the out-of-Africa model of human population history. Reich and colleagues speculate there must have been some sort of event to cause the long LD—for instance recolonization by a small group—and have calculated that the extent of LD observed may be due to a major population bottleneck about 27,000 to 53,000 years (800 to 1600 generations) ago, and they suggest as few

as 50 individuals may have founded the population from which most people of Northern European descent have arisen. While the details of this actual event remain murky, Reich says, “In trying to answer questions of medical genetics we really stumbled on something interesting, and I think it helps answer an important problem of history.”

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counterfeit drugs to efforts on the part of the elderly and others to obtain needed drugs at lower prices, vowing to “tackle affordability.”

FDA and several other agencies, including the US Customs Service and the Drug Enforcement Agency, share responsibility for regulating the import of illegitimate prescription drugs. However, officials from these agencies agree that personnel and budget shortages make that task very challenging, particularly where it involves imports through the mail of small lots of materials to local pharmacies or individuals. FDA officials promise to remain “vigilant” and to strengthen several pilot programs aimed at improving detection of such imports that could lead to better enforcement practices.

Meanwhile, during the June hearing, several industry representatives agreed that federal regulatory agencies have inadequate resources for dealing with the expanding counterfeit drug problem, calling it global in scope, and noting that it involves sophisticated if bogus manufacturing operations in countries such as China and India, with channels for importing products to the US through Mexico and Canada. Industry representatives also urge Congress not to approve programs that would permit easier reimportation of prescription drugs from Canada that are US-made, warning that such programs, while intended to save money for US citizens because such drugs are lower-priced in Canada, would further weaken current safeguards against counterfeit products.

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Fake biotech drugs raise concerns

Several biotechnology companies found themselves targeted by drug counterfeiters during the first half of this year in a series of incidents that not only are costly for the companies but also are raising concerns among members of Congress and officials at the US Food and Drug Administration (FDA; Rockville, MD) and other agencies responsible for ensuring that therapeutic products available to consumers are what they are supposed to be. This flow of illicit therapeutic drugs, much of which is being imported illegally, is another factor that plays into a broader debate about drug pricing and prescription drug coverage that consumers, industry representatives, and members of Congress and the Bush administration are expected to resume in the months ahead.

While the US government spends huge sums of money trying to prevent illegal imports of narcotics such as heroin and cocaine, little goes into preventing imports of illicit prescription drugs. Although little can be said as to how extensive this latter activity may be, several incidents this past May suggest that it is surprisingly robust.

Thus, for example, authorities discovered several counterfeit therapeutic biotech products and joined with company officials to transmit notices about how to identify the bogus products. Affected products included Serono’s (Norwell, MA) Serostim and Genentech’s (South San Francisco, CA) Nutropin—their respective versions of somatropin for use in treating AIDS patients for wasting syndrome—and Amgen’s (Thousand Oaks, CA) Neupogen, its version of granulocyte colony stimulating factor that is used for preventing infections among neutropenic patients with cancer or other diseases.

Somatropins reportedly are widely used off-label by body builders and for cosmetic purposes, meaning there is a ready underground market for distributing them without users obtaining prescriptions. In any case, the producers of the fake therapeutic drugs used vials, labels, and other materials

that very closely resemble the genuine product and its standard packaging materials—making it very difficult for unsuspecting physicians or others to determine what was in hand before putting it to use. Despite the obvious risks to end users, no deaths of serious adverse effects stemming from these incidents have been reported.

Although the source of these three sets of faked materials is not known, “such a cluster of counterfeits has not been seen for years in this country,” says Representative WJ Billy Tauzin (R-LA), who chairs the House Committee on Energy and Commerce, whose Oversight and Investigations Subcommittee held a hearing, “Growing Risks Associated with Imported Pharmaceuticals,” early in June. “Unless we find new effective solutions. . . it is only a matter of time that these uncontrolled imported drugs will lead to an epidemic that will kill, maim, or severely sicken people.” He links this recent surge of

Italian public votes out anti-GMO Greens

After a tense electoral campaign marred by anti-GMO issues, Italy’s center-left coalition government—the first to include Green Party ministries—was defeated in the national election on 13 May. The extreme anti-GMO antics of the world’s first Green agricultural minister Alfonso Pecoraro Scanio are widely blamed for the demise of the Green party in Italy, and the saga presents a lesson to Green parties elsewhere in Europe.

Since taking office in May 2000, Pecoraro Scanio has become the most notorious anti-GMO minister in Europe. He banned products derived from GM corn commercialized elsewhere in the EU (*Nat. Biotechnol.* 18, 1137, 2000), he pressed the Italian environment minister not to drop the European de facto moratorium on GMOs, and he persuaded the European Council of ministers not to approve a new directive on vines as it

showed some softening toward GM varieties (*Nat. Biotechnol.* 19, 15, 2001). But his political demise began in earnest last autumn, when he suspended ministerial funds for agbiotech research. The move prompted a protest by top scientists, forcing him to back down in front of the prime minister (*Nat. Biotechnol.* 19, 293, 2001). Luigi Manconi, former secretary of the Green Party, says it was this protest that caused a great loss of historical support for the party, particularly from the intellectual middle-class.

Pecoraro Scanio remained undeterred, however, and GMO controversies continued to dominate his last few months in office. Next, he set about alienating farmers. Commercial growing of GM corn and GM soybeans is not allowed in Italy, but the country depends heavily on seeds imported from the US and Argentina, where GM vari-