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WRITTEN TESTIMONY

OF

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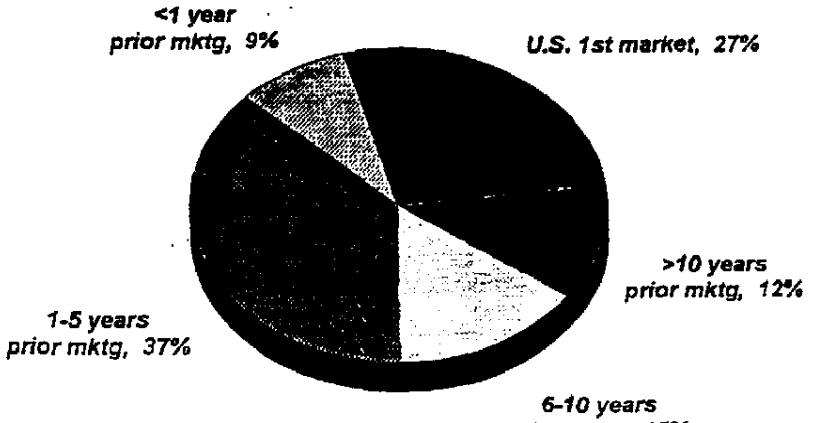
Implications of Regulatory Stringency

Some have argued that in the United States, the stringency of the FDA's new drug approval requirements contribute to the high cost and excessive time required to bring new pharmaceutical products to market (Wardell, 1973; Cullen, 1983). One putative outcome of this regulatory stringency has been the well-documented "drug lag," that is, the delay in the availability of new drugs in the United States relative to other industrialized countries (Wardell 1973, 1978; Kaitin et al., 1989). Recent evidence of a delay in new drug availability in this country is presented in Figures 3 and 4.

Figure 3 shows the percentage of new drugs approved in the United States during the period 1987 through 1992 that were marketed first the United States, as well as the percentages for drugs available in foreign markets less than one year, one to five years, six to 10 years, and more than 10 years prior to U.S. approval.

Figure 3: Prior, Foreign Marketing of New Drugs Approved in the United States, 1987-1992

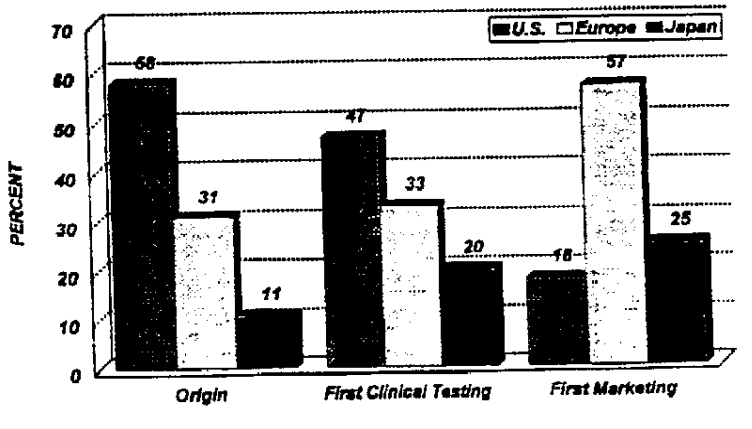


Source: Tufts Center for the Study of Drug Development, 1995

While 27% were first introduced in the United States, 54% were available one or more years in a foreign market before U.S. approval, and 12% were available more than 10 years prior to U.S. approval. It should be noted that this analysis includes marketing in any foreign country; undoubtedly some of those countries have regulatory standards for drugs that are lower than those in the United States. Moreover, it is not reasonable to expect any country to be the first to market all drugs approved in that country. Nonetheless, the large number of new drugs introduced first outside the United States and the long delay between first foreign marketing and U.S. approval suggest that U.S. consumers experience delayed access to many potentially useful medicines.

Figure 4 shows the site of origin, first clinical testing, and first marketing for 36 biopharmaceutical products approved in the United States, Europe, and Japan through June 1992 (Bienz-Tadmor, 1993). Whereas 58% of these products originated in the United States, and 47% began clinical testing in this country, only 18% were first marketed here. In contrast, 57% were first marketed in Europe and 25% were first marketed in Japan.

Figure 4: Origin, First Clinical Testing, and First Marketing of Approved Biopharmaceuticals in the United States, Europe, and Japan



Based on the 36 biopharmaceutical products approved in all three markets by June 1992
Source: Bienz-Tadmor, BioTechnology 1993; 11:168-172

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