CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE

April 15, 2005

S. 172

A bill to amend the Federal Food, Drug, and Cosmetic Act to provide for the regulation of all contact lenses as medical devices, and for other purposes

As reported by the Senate Committee on Health, Education, Labor, and Pensions on March 9, 2005

S. 172 would amend the Federal Food, Drug, and Cosmetic Act (FDCA) to require that the Food and Drug Administration (FDA) regulate all contact lens products as medical devices.

FDA currently regulates all contact lenses as medical devices except for decorative, non-corrective lenses, which FDA currently regulates as cosmetics. S. 172 would deem all contact lenses to be medical devices under the FDCA. Based on information from FDA, CBO expects that the additional cost for FDA to regulate decorative contact lenses as medical devices beyond its cost to regulate such products as cosmetics under current law would be negligible. Assuming the availability of appropriated amounts, CBO estimates that implementing S. 172 would cost FDA less than $500,000 annually.

CBO expects that changing the regulatory classification of decorative, non-corrective lenses to medical devices would likely lead to FDA requiring that those products be available only by prescription. (For decorative, non-corrective lenses, a prescription-only label would require the oversight of an eye care professional to ensure proper fitting and use.) In response, we anticipate that the Federal Trade Commission (FTC) would expand its regulation of prescription contact lenses to include decorative non-corrective contact lenses. Based on information provided by the FTC, CBO estimates that implementing S. 172 would not have a significant impact on spending subject to appropriation for that agency.

The legislation would not affect direct spending. There would be potential for higher revenues through penalties imposed by FDA and the FTC for violations of federal laws under their respective jurisdictions related to contact lenses. Such collections of civil penalties are recorded in the budget as revenues. However, based on information provided by the agencies, CBO expects that revenues from any penalties collected as a result of enacting S. 172 would be negligible.

S. 172 contains no intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA) and would impose no costs on state, local, or tribal governments. However, the bill would impose private-sector mandates on sellers, prescribers and manufacturers of decorative non-corrective lenses by making them subject to more stringent federal regulatory requirements for medical devices. CBO estimates that the direct costs of the mandates in the bill would not exceed the threshold established in UMRA ($123 million in 2005, adjusted annually for inflation) in any of the first five years the mandate would be effective.

A mandate would be imposed on sellers and prescribers because, as medical devices, such contact lenses would more likely require prescription verification. CBO expects that prescribers of decorative, non-corrective lenses would have to provide the patient with a copy of the prescription and to verify the prescription to third-party manufacturers. Since eye care professionals need only return the call of a third-party manufacturer if the prescription the manufacturer has is wrong, CBO estimates that the costs to these entities would be insignificant.

S. 172 also would impose a private-sector mandate on manufacturers. Based on information from industry and government sources, CBO estimates that most major manufacturers already produce decorative, non-corrective contact lenses under standards that would meet the tighter FDA requirements. For the remaining manufacturers, CBO estimates that the cost of upgrading production processes and obtaining FDA approval would not be significant.

The CBO staff contacts for this estimate are Julia Christensen and Melissa Zimmerman (for the federal budget impact), Leo Lex (for the state and local impact), and Meena Fernandes (for the private-sector impact). This estimate was approved by Peter H. Fontaine, Deputy Assistant Director for Budget Analysis.