

## APPENDIX A

### SEC. 3507. PRESENTATION OF PRESCRIPTION DRUG BENEFIT AND RISK INFORMATION.

(a) **IN GENERAL.**—The Secretary of Health and Human Services (referred to in this section as the “Secretary”), acting through the Commissioner of Food and Drugs, shall determine whether the addition of quantitative summaries of the benefits and risks of prescription drugs in a standardized format (such as a table or drug facts box) to the promotional labeling or print advertising of such drugs would improve health care decisionmaking by clinicians and patients and consumers.

(b) **REVIEW AND CONSULTATION.**—In making the determination under subsection (a), the Secretary shall review all available scientific evidence and research on decisionmaking and social and cognitive psychology and consult with drug manufacturers, clinicians, patients and consumers, experts in health literacy, representatives of racial and ethnic minorities, and experts in women’s and pediatric health.

(c) **REPORT.**—Not later than 1 year after the date of enactment of this Act, the Secretary shall submit to Congress a report that provides— (1) the determination by the Secretary under subsection (a); and (2) the reasoning and analysis underlying that determination.

(d) **AUTHORITY.**—If the Secretary determines under subsection (a) that the addition of quantitative summaries of the benefits and risks of prescription drugs in a standardized format (such as a table or drug facts box) to the promotional labeling or print advertising of such drugs would improve health care decisionmaking by clinicians and patients and consumers, then the Secretary, not later than 3 years after the date of submission of the report under subsection (c), shall promulgate proposed regulations as necessary to implement such format.

(e) **CLARIFICATION.**—Nothing in this section shall be construed to restrict the existing authorities of the Secretary with respect to benefit and risk information.