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FDA could analyze public health consequences of its decisions better

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A new report from the National Research Council lays out a framework for the U.S. Food and Drug Administration to systematically evaluate and compare the public health consequences of its decisions concerning a wide variety of products. Moreover, the risk-assessment framework provides a common internal language to discuss potential options and draws extensively on well-vetted risk literature to define the relevant health dimensions for FDA decision making.

FDA must make decisions daily, from determining whether a certain drug should be approved to deciding what resources should be allocated for inspections of food production facilities, the report says. The committee that wrote the report said the framework is intended to complement, rather than replace, other risk-based approaches at FDA and is designed to serve as a general guide while providing consistent risk information to support a variety of decisions.

The new framework, while easily articulated, would require FDA to invest thought and effort to implement properly. It consists of three steps: careful definition of the decision options, estimation or characterization of the public health consequences of each option, and structured comparison of the consequences to inform decision makers and the public.

The committee applied the risk-characterization framework to four hypothetical case studies: deciding whether to withdraw a vaccine from the market, evaluating the potential public health consequences of

foodborne illness, helping determine testing priorities for a laboratory, and choosing whether to improve existing surveillance of two medical devices. For each, the committee illustrated how its framework could be applied; defined the specific options to be compared; developed a risk-attribute table to characterize the public health consequences of alternative decisions; and illustrated how the risk characterizations could be used to compare the specific decision options.

The committee recognized that precise predictions of different consequences may be difficult to develop in cases where data are lacking or scientists are uncomfortable making the necessary judgments. However, decisions in which risk information could be valuable are made regularly. The committee recommended that FDA use experts who are trained in and comfortable with decision analysis, risk assessment, risk management, and specifically the assessment of uncertainties to facilitate the use of the framework.

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