

The current tacit no-risk approach to regulating thalidomide fails to evaluate the health risks of those currently afflicted with leprosy or macular degeneration and the benefits associated with treating these illnesses. Based on the congressional risk-risk and risk-benefit frameworks, we recommend that the FDA approve the use of thalidomide in conjunction with strict guidelines for prescribing, dispensing, and monitoring use of the drug. Furthermore, based on the equity, efficiency, administrative simplicity, transparency, and effectiveness of policy options for ensuring a source of thalidomide, the FDA should recommend that Congress exempt manufacturers from product liability without providing a government payout for costs associated with birth defect caused by thalidomide.

THALIDOMIDE APPROVAL ASSESSMENT

No-risk framework: Thalidomide has been convincingly implicated as a cause of birth defects when taken during the first trimester of pregnancy. This health risk would not be tolerated under a no-risk decision framework. The current position, which maintains the ban on thalidomide, deprives many Americans with leprosy or macular degeneration of an opportunity to live a healthy life. The FDA is, in effect, allowing the potential health consequences to the unborn to have greater sway over policy than the quantifiable health consequences to citizens alive today. When such consequences recommend opposing actions, the use of risk-risk framework or a risk-benefit framework is more appropriate for deciding on the best course.

Risk-risk framework: Drugs inherently pose health risks in conflict with their benefits. The FDA must balance the risk of taking the drug against the risk of not having access to the drug. Without access to thalidomide, death and blindness are the probable result to those afflicted with leprosy or macular degeneration. Access to thalidomide introduces the risk of birth defects associated with the drug. This high-impact consequence is of relatively low

probability when users with the target conditions are properly informed and screened. FDA should license thalidomide with strict guidelines for dispensing and monitoring patients where the possibility of pregnancy and risk of birth defects exists.

Risk-benefit framework: The benefits associated with access to a drug must also be considered in the FDA's regulatory decisions. Those that are cured through the use of this "miracle" drug—so called because there are no effective substitutes—can return to a productive life rather than drain the resources of the insurance and health care systems. The risk of birth defects can be controlled by prescribing birth control to women who decide to take thalidomide to treat leprosy or macular degeneration. Current birth control implants are highly effective and will significantly reduce the risks of birth defects caused by thalidomide.

ASSESSMENT OF POLICIES FOR ENSURING A SOURCE OF THALIDOMIDE

The recommendation to approve thalidomide for these two specific purposes must be coupled with a means of ensuring that a source exists. Manufacturers will not produce the drug if they will be liable for damages should birth defects occur when a pregnant woman accidentally use the drug. This could occur despite proper labeling and education because of a failure of birth control, a failure to use birth control, or the lag encountered before discovering pregnancy and cessation of treatment. Based on the following analysis, the FDA should recommend that Congress eliminate this obstacle by exempting manufacturers from such lawsuits.

Equity: An exemption from product liability would enable manufacturers to produce an effective and affordable drug for those afflicted with leprosy or macular degeneration. Those with these illnesses will be able to weigh the risks and benefits associated with the drug. The public would not be responsible for potentially large medical payouts by either the government or pharmaceutical companies.

Efficiency: An exemption from product liability will minimize the final cost of providing thalidomide because manufacturers would not be forced to build the cost of litigation into the wholesale price of thalidomide (or other products).

Administrative simplicity: An exemption from product liability would eliminate the large transaction costs associated with liability lawsuits or federal government settlements.

Transparency: An exemption from product liability clearly illuminates the federal government's commitment to provide treatment for leprosy and macular degeneration. However, it may appear to the public that the federal government is showing favor to pharmaceuticals by allowing them to shed responsibility from the risks associated with drugs. This can be countered with appeal to the specific restrictions on using the drug and contrasted with the widespread use of thalidomide in the past before the dangers were known.

Goal Attainment: An exemption from product liability will ensure a source for thalidomide with or without government guarantees to cover expenses incurred by those who may suffer birth defects as a result of use.

The exemption is consistent with other liability exemptions, such as those for vaccines that have similar social benefit but high impact, low-probability risks. However, the FDA should not recommend Congress guarantee expenses because it is not required to achieve the goal.

In summary, the FDA should approve the use of thalidomide with strict guidelines for prescribing, dispensing, and monitoring use of the drug. Furthermore in order to ensure a source for thalidomide, the FDA should recommend that Congress exempt manufacturers from product liability with no payout for consequential damages that may result from misuse.