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EDITORIAL

F.D.A.'s Secret Files

The Food and Drug Administration has created a task force to recommend ways to reveal more information about how the agency makes decisions about the safety and efficacy of drugs and medical devices. Any move in the direction of greater transparency is bound to help both patients and their doctors better understand the risks and benefits they face.

At the insistence of industry, and its claims of proprietary information, the F.D.A. often sits on data that raise questions about a drug's safety or therapeutic value. The consequences for some patients can be severe.

As Gardiner Harris reported in The Times on Tuesday, in recent years, the F.D.A. failed to inform the public that a widely prescribed heartburn drug was especially toxic to babies, that a diabetes drug and a painkiller increased heart attack risks and that antidepressants increased suicidal thoughts and behavior in youngsters.

The agency is hemmed in by laws restricting its ability to release trade secrets and internal agency records. But there seems little doubt that it has been overly cautious and that public safety has suffered as a result.

We urge the task force to lean aggressively in the direction of releasing as much information as possible about how a drug or device fared in clinical trials, the basis for approving or recalling products and any enforcement action taken against a company. If some laws and regulations need to be rewritten, that is a small price to pay for greater transparency.

There may be legitimate data that need to be protected — possibly the exact formulation of a drug, for example — but the overriding goal should be to give doctors and patients the maximum amount of information while carving out a narrow exception for carefully defined trade secrets.

The F.D.A. is far from infallible. The more information made available to outside experts, the more likely that a drug or device will be regulated and used wisely.