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Drugs Kennedy Needs

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Senator Edward M. Kennedy's (D-Mass.) recent diagnosis of a glioma, a malignant brain tumor, puts the spotlight on Food and Drug Administration (FDA) drug approval policies. The authors argue that the progress being made in clinical drug trials for glioma is too slow. The FDA's failure to approve some of the most promising drugs comes at the expense of victims who could really benefit from taking them and who are invisible to all but a few.

Senator Kennedy is expected to recover from his brain tumor surgery without any serious side effects, thankfully. And while the spotlight is on his recovery, the news of his malignant brain tumor should also shed some light on drug approval policies.

Senator Kennedy suffers from a malignant brain tumor, a glioma. There are at least two drugs approved to treat glioma tumors, and there is research being done to find newer treatments. Yet, the progress made in these clinical drug trials for glioma is too slow. For example, the National Institute of Health's website on clinical trials lists twenty-three studies of Avastin for glioblastoma, the most dangerous form of glioma brain tumors, but only five of the trials are active, and sixteen still are recruiting patients.

Avastin is an angiogenesis inhibitor, meaning that it suppresses the creation of new blood vessels that cancer cells need in order to grow and become dangerous. The fruit of a decades-long search by the biotech firm Genentech, Avastin finally secured FDA approval in February 2004 to treat colorectal cancer. Since then, Avastin has been approved to treat other cancers and has been scrutinized in another hundred or so clinical trials—including one on brain tumors, with results due later this month.

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Competitors are developing their own angiogenesis inhibitors—Pfizer has one called Axitinib, for example. These drugs will probably be tested in brain tumor trials too, if they are successful in early trials. Also promising are therapeutic vaccines, including one from Pfizer and its biotech partner, Avant, and another from Northwest Biotherapeutics. Both vaccines energize the immune system to attack brain tumors and have promising results in clinical trials. But we need progress at the FDA as well.

While there are those who believe the FDA should be even tougher in approving new drugs, while devoting ever more attention to safety, we think the FDA already is too restrictive. The FDA's failure to approve some of the most promising drugs comes at the expense of victims who could really benefit from taking them and who are invisible to all but a few.

Extraordinary attention has been paid to the safety of Vioxx and antidepressants—demonstrating the eternal truth that the FDA has much more to lose when approved drugs cause problems than when new drugs take too long to get approved. There should be more public outrage over the FDA's failure to approve new cancer drugs such as Provenge, a therapeutic vaccine that was strongly recommended for approval by an FDA expert advisory committee. Surely something is wrong with a regulatory environment in which the FDA waited

nearly six years—six years—after the European Union to approve the widely prescribed cancer drug Eloxitan.

The costs of the FDA's tough drug approval standards and thus delay in approving drugs may not be easy to see, but they are very real—not just in terms of patient health but also as a factor in research and development costs. Taking account of the inevitable failures along the way, the average cost of bringing a new drug all the way from test tube to market is approximately $1 billion.

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Unfortunately, although he has advocated some useful proposals, Senator Kennedy is among the politicians who support stricter FDA regulation and other measures aligned against drug development. The recently enacted FDA Amendments Act, for example, requires costly and unnecessary postapproval safety studies, among other things, and threatens onerous restrictions on the use of new cancer drugs. Many of these politicians also oppose the FDA's plan to preempt many state tort lawsuits over FDA-approved drug warnings. Brought by plaintiffs claiming injury by approved drugs, these lawsuits let juries second-guess the FDA in order to force manufacturers to add yet more warnings to a drug's label, even when the FDA thinks the warnings will discourage valuable uses of the drug.

Especially worrisome is Senator Byron Dorgan's (D-N.D.) drug importation bill. It would force pharmaceutical firms to supply their drugs to America's market at the lowest price set by drug price controllers in the European Union. The profits necessary to motivate the development of new cures would disappear.

Finally, there is support for legislation to let the Centers for Medicare & Medicaid Services set drug prices instead of allowing the market to set Medicare drug costs. This is yet another way of suppressing the rewards from innovation.

No one can say whether more incentives for rapid drug development would have led to a difference in Senator Kennedy's prognosis. But we do know that many people would be alive today if more rational drug approval policies were in place.