FDA Rejects Expert Panel Recommendation, Blocks OTC Switch for Plan B Emergency Contraception

The Food and Drug Administration (FDA) on May 6 overruled the recommendation of its own expert advisory panel and declined to approve over-the-counter (OTC) status for the postcoital contraceptive known as Plan B. In a letter to Barr Pharmaceuticals, Steven Galson, acting director of the FDA's Center for Drug Evaluation and Research, said that the company had failed to show that Plan B can be used safely by younger teenagers without medical guidance, noting that the company's study of Plan B in actual use included just 29 women aged 14–16 and none younger than 14—a sample he said was too small to support conclusions about safety. The FDA told Barr that, before the drug could be sold without a prescription, the company would have to provide additional data showing that Plan B can be used safely by women younger than 16 or propose a plan that would allow women aged 16 and older to buy the drug OTC while maintaining prescription-only status for younger teens.

Speaking in a teleconference on May 7, Galson acknowledged that the decision was far from typical. Normally, when the FDA evaluates a drug for safe OTC use, it looks at whether it is toxic or addictive, assesses its side effects and considers how it is absorbed, distributed, metabolized and cleared by the body. The FDA's decision against Plan B, however, was based on concerns that go well beyond medical safety, taking into account the impact its availability OTC might have on teen sexual behavior. Galson said he worries that if young women had easier access to emergency contraception, some might be more likely to have sex without condoms, exposing themselves to an increased risk of sexually transmitted infections.

Reactions

Outrage over the FDA's decision boiled in Congress as over 40 members of the House sent a letter on May 7 to acting FDA Commissioner Lester Crawford, charging the agency with putting politics before science. At a hastily called news conference, Reps. Louise M. Slaughter (D-NY) and Christopher Shays (R-CT) called on Galson and Crawford to resign and on the General Accounting Office to investigate the process by which the FDA made its decision. "The FDA's decision to ignore its own scientific advisory board and its own staff clearly demonstrates that the leadership would rather pander to conservative interests than protect women's health and well-being," said Slaughter. Legislation to require the FDA commissioner to investigate the Plan B decision-making process was introduced by Rep. Carolyn B. Maloney (D-NY) and 15 of her colleagues a few days later.

Wendy Wright, senior policy director for the conservative group Concerned Women for America, told the Associated Press that the FDA was "right to be cautious about having a potent drug that can harm women next to candy bars and toothpaste." Many of the leading medical organizations, however, decried the decision as tragedy for American women. The American College of Obstetricians and Gynecologists issued a strongly worded statement calling the FDA's action "morally repugnant" and "a dark stain" on the reputation of the FDA as an evidence-based agency.

Outlook

Barr representatives say that the FDA's decision will delay its product's introduction to store shelves, but that they will be able to address the FDA's objection in a matter of "weeks or months, not years." Many experts in the field, on the other hand, are concerned that the FDA's suggested pathways to approval, in reality, may be dead-ends, and that approval is unlikely any time soon. New safety data could take years to collect—assuming such studies are even feasible. A number of methodological challenges make it difficult to study the drug's impact on younger teens, including the reality that very few teens 15 and younger seek emergency contraception.

Moreover, critics question the feasibility and perhaps even the legality of a plan to make emergency contraception available OTC to older women but only by prescription to those under 16. Never before has the FDA approved a drug in the same dosage for the same indication both as a prescription-only and as an OTC product, and it is unclear whether the agency in fact has the statutory and regulatory authority to market Plan B under this dual status. At a minimum, such an approach would present significant implementation challenges.

The FDA's decision, at least temporarily, returns leadership on expanding access to emergency contraception to the states. In May, Maine enacted legislation allowing pharmacists to provide emergency contraception without a prescription, bringing to six the number of states that grant pharmacists this authority under collaborative practice agreements or in accordance with state-approved protocols. As of mid-May, similar measures were pending in four additional states.
—H. Boonstra