The Daily Dish

A Defective Lawsuit

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At one level, it is a familiar tale. In 2001, the Food and Drug Administration (FDA) approved a Gilead treatment for human immunodeficiency virus (HIV) based on the compound tenofovir disoproxil fumarate (TDF). (Say that three times real fast!) In 2015, the FDA approved a successor drug based on tenofovir alafenamide (TAF). Gilead is being sued in California on the grounds that it delayed introducing the TAF drug in order to milk its patent on the TDF drug, keeping prices high and extracting undeserved profits.

Regular readers of Eakinomics will recognize the tensions and tradeoffs of the need for patent protection and the pricing power it bestows to incentivize innovation versus the desire of consumers to have cheap access to modern therapies. The existing system does its best to mediate among these goals. From this perspective, another lawsuit has no merit.

But there is a twist: The lawsuit against Gilead is being brought under product liability law, arguing that Gilead should have rolled out the TAF alternative treatment sooner because it has fewer bone and kidney side effects. In effect, the TDF was a defective product. Eakinomics will not try to sort out the defect claims other than to point out that both drugs were approved as safe by the FDA and the evidence of reduced side effects is contested. Nevertheless, a judge ruled that Gilead could be sued under this theory.

The scary issue is the implication of setting this precedent. Narrowly, this would eliminate the incentive for pharmaceutical companies to improve their products. Why do that when all it buys you is a product liability suit? That is terrible for incentives. Gilead argues in its appeal that the ruling would “create virtually limitless and unpredictable liability with no additional incentive for safety” and “weaponize the uncertain and winding path of scientific inquiry.”

The damage to drug development would be enormous. But the precedent would not be limited to drugs. In an amicus brief filed in the case, the U.S. Chamber of Commerce argues: “Numerous industries would be harmed by the imposition of tort liability on companies that fail to develop and successfully commercialize improved versions of their existing products. A duty to develop the safest products possible is a duty that seems to have no logical limit or predictable stopping point. Put otherwise, if there were in fact a legally enforceable duty to maximize safety by developing the safest product that achieved a particular goal, then it would seem to be impossible for a manufacturer to know whether or when it had satisfied such a duty. In that sense, the duty proposed by Plaintiffs appears to be a duty that it is impossible for anyone to predictably satisfy. The uncertain scope of liability would by paralyzing.”

There’s certainly something defective here – the legal rationale behind this lawsuit.