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Laura Musselwhite and Bryan Collingsworth
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Societal Impact Of Extending Market Exclusivity For Conventional Drugs

We are concerned that Dana Goldman and colleagues (Jan 2011) prescribe a major change in data exclusivity for conventional drugs based solely on their “global pharmaceutical policy model” projection that fifty years from now, the change may yield a quality-unadjusted life expectancy increase of less than two months.

The model relies on several problematic assumptions, particularly that robust pharmaceutical industry revenues necessarily promote drug innovation. From 2005 through 2009, the Food and Drug Administration approved 39 percent fewer new drugs than were approved between 1995 and 1999, despite persistently high revenues reported by the pharmaceutical industry over these time periods.

Further, the model does not incorporate an escalated need for the development of specific alternatives to existing therapies, such as new antibiotics for increasingly multidrug-resistant organisms and less toxic agents to address neglected tropical diseases that are a reemerging threat

in the United States.

The model also predicts that increasing exclusivity will lead to an additional 228 drugs by 2060, but it cannot define the societal impact value of those new drugs. Data exclusivity incentives may be subject to misuse if minor changes to existing drugs receive brand-name status and are granted an additional twelve years of market exclusivity. This would yield the opposite of the intended effect by discouraging innovation and competition.

We propose that policy makers should not focus on more protections for one of our most recession-resilient industries, using an imperfect model’s prediction of a narrow cost-benefit ratio that will not become evident for fifty years. Rather, we must reexamine whether current incentives for drug development are truly driving innovation while simultaneously addressing the acceleration of health care costs and the US deficit.

Laura Musselwhite and
Bryan Collingsworth
*Universities Allied for
Essential Medicines*
BERKELEY, CALIFORNIA