

Old drugs need 'repurposing' for new uses, physician says

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Overly restrictive intellectual property laws devalue the "repurposing" of existing medications for new uses, slowing their availability as life-saving treatments, a Portland researcher contends.

S. Paul Berger, M.D., assistant professor of psychiatry and behavioral neuroscience in the Oregon Health & Science University School of Medicine and the Portland Veterans Affairs Medical Center, writes in a letter appearing in the current issue of the journal *Nature* that "economics and patent laws" keep pharmaceutical companies from finding new uses for old drugs.

Instead, drug companies "reinvent the wheel" by spending millions of dollars to develop new drugs for diseases that existing drugs have already been shown to be effective against in off-label uses, Berger believes. As a result, new drugs take years to reach consumers who need them as they undergo lengthy testing in clinical trials required by the Food and Drug Administration, and the development costs are passed on to consumers.

In his *Nature* letter, Berger cites recent comments by Federick Goodwin, M.D., former director of the National Institute of Mental Health, who said lithium remains underused in high-risk patients, despite strong evidence that, unlike most other psychiatric medications, it significantly lowers the risk of suicide in people with manic-depressive illness.

"Similarly," Berger writes, "although folic acid has been shown to increase the efficacy of antipsychotic medications in certain patients, a



psychiatrist at a recent meeting told me that he could not persuade his colleagues to prescribe this comparatively harmless vitamin."

Berger suggests that such difficulties "stem from the failure of intellectual property laws to assign sufficient value to 'use' patents, involving new uses for old medications. In effect, a discovery of immense human value — preventing suicide — is assigned a negligible economic value that fails to motivate the pharmaceutical industry to develop the drug."

He adds that the "antiquated laws governing new uses for existing medications need to be reformed if lifesaving discoveries are to be exploited."

To prove his point, Berger is about to publish two papers demonstrating new uses for old drugs. One points to an "alpha-1 antagonist" that's been used to treat sleep disturbances and nightmares of post-traumatic stress disorder, but which shows promise in preventing brain damage caused by traumatic stress sufficient to precipitate PTSD or relapse of schizophrenia and depression. The other is a "sigma-1 antagonist" once tested as a schizophrenia treatment, but which has been found to suppress the involuntary "dyskinetic" (abrupt and awkward) movements that are disabling side effects of taking levodopa for Parkinson's disease over long periods.

But Berger acknowledges that getting drug companies to pick up these new uses for old medications is an uphill battle.

"There are so many off-label uses for medications that people come up with, but the drug companies have no financial incentives to develop generic drugs for new indications. There's no money in it," Berger said.

Such attitudes are creating a logjam in the movement of discoveries



from the laboratory to the clinic, he added. "Extrapolating from bench progress, the pharmaceutical industry should be growing the way the computer industry did in the 1980s, fueling an economic boom. The number of new drugs for my veteran patients with psychiatric illnesses from Iraq or earlier conflicts is much less than I expected and declining at a time where it should be increasing."

Source: Oregon Health & Science University

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