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3 ideas could help rejuvenate drug discovery and speed the transition to more effective, highly specific biologic agents

Innovation deficit disorder Psychiatry needs 'disruptive' new drugs

Clinical psychiatry, like other medical specialties, eagerly awaits treatment breakthroughs. Despite the availability of many pharmacotherapies, even common illnesses such as diabetes, hypertension, and bipolar disorder cannot be cured.

Until investigators unravel a disease's pathophysiology, treatments tend to remain symptomatic. Molecular genetics research ultimately may revolutionize the treatment of serious body and mind disorders, but how long must we wait?

As naïve medical students in the 1970s, my friends and I believed cures certainly would be discovered before the new millennium for cancer, arthritis, Alzheimer's dementia, schizophrenia, diabetes, major depression, and anxiety. Although progress has been made, the pace of developing effective new treatments has been much slower than we expected.

As a researcher, I understand why brave new treatments are elusive. Even so, I keep hoping to see "disruptive" discoveries that will bring solutions to our patients' suffering. Psychiatry needs a surge in pharmacologic innovations to advance from decades-old, serendipitously discovered, partially effective drugs to highly specific and effective biologic interventions.

Where will these desired breakthroughs come from? The National Institute of Mental Health (NIMH) does not have the budget to develop new drugs for psychiatry. The pharmaceutical industry—on which psychiatry is almost entirely dependent for new medications—seems to have stalled. Drug companies are complex, for-profit enterprises that employ tens of thousands of researchers to discover, test, and develop new drugs under an increasingly stifling web of regulatory controls.

Although drug companies have made progress against disease, the public has a rather negative view of them. Americans seem to appreciate that drug discovery is arduous, time-consuming, and

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costly, but they hold pharmaceutical companies to a different standard than other corporations. Practically everyone applauds when a high-tech or apparel company makes huge profits, yet when a pharmaceutical company does so there is outrage. Like it or not, creating new medications requires massive investment, and—other than taxes—profits are the only way to provide the resources for psychopharmacology research and development (R&D).

Perhaps the lull in new psychopharmacologics reflects escalating pressures on drug companies:

- Patent life is limited.
- Product development takes years and significant financial risk (only 1 in 10,000 new molecular entities makes it to market).
- Liability costs are skyrocketing because of unrealistic public expectations for new medications: high efficacy and no side effects.

Drug companies compound their problems by overspending on marketing and lobbying, and they often merge with one another to create behemoths that stifle innovation. No wonder we see so many reformulations of existing products and “me-too” drugs instead of high-risk, high-cost novel approaches to disease management.

What practical solutions could rejuvenate drug discovery? The answers are not simple, but consider these ideas:

- Extend by several years the patents on breakthrough (novel mechanism, first-in-class) drugs, and during this extension earmark a good chunk of profits for R&D.
- Limit punitive damages from lawsuits related to breakthrough medications to remove this impediment to innovation.
- Create incentives for drug companies to collaborate with NIMH researchers to translate neurobiologic and molecular genetics discoveries into innovative, biologically specific agents for psychiatric brain diseases.

Forging private-public collaborations may be a winning formula for all, with seriously afflicted patients as the ultimate beneficiaries of new drugs for their unmet needs.



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