United States (US) agencies, particularly the Food and Drug Administration (FDA), have been at the forefront in attempting to make pharmacogenetic testing a reality. Therefore, understanding US regulations and practices is relevant in other countries. Past and present pharmacogenetic testing in psychiatry in the US can be summarized in 3 phases: a) the fear phase (early 2000s), when pharmaceutical companies were afraid of pharmacogenetic testing; b) the failure phase (late 2000s), when the first commercialized pharmacogenetic tests failed and c) the hype phase (currently) when non-validated commercialized pharmacogenetic tests are aggressively marketed.

Regarding the present, the author’s view is that pharmacogenetic testing can help in a few psychiatric cases: 1) before starting: a) carbamazepine in patients with Asian ancestry (HLA-B*15:02 testing), or b) tricyclic antidepressants (CYP2D6 and CYP2C19 genotyping); and 2) occasionally when seeing lack of efficacy or adverse drug reactions with selective serotonin reuptake inhibitors, venlafaxine, pimozide, aripiprazole, brexipiprazole, iloperidone, risperidone, clozapine, or atomoxetine (CYP2D6 and/or CYP2C19 genotyping). Commercial tests should not be ordered for: 1) CYP1A2, CYP2B6, CYP3A4 or CYP3A5 genotyping; 2) brain neurotransmitter and/or transporter genotyping; or 3) diagnosing schizophrenia, depression or bipolar disorder.

Regarding the future, US marketing of pharmacogenetic tests requires: 1) understanding the pharmacological complexity of drug response, 2) modifying the oversight of non-FDA regulatory agencies, 3) clarifying the FDA’s role, and 4) promoting innovative marketing. The incorporation of pharmacogenetic tests into long-term practice requires: 1) not jeopardizing pharmacogenetic testing by short-sighted marketing of non-validated tests, 2) educating prescribers about benefits, 3) educating patients about limitations, and 4) considering the differences between isolated testing and generalized testing incorporating big data.

Selected Publications: