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Introduction

Scienti c and technologic advancements in uence decision making by drug discovery and development scientists, clinicians, and regulators. e American College of Clinical Pharmacology (ACCP) uses these scienti c milestones to communicate its understanding of

e Link Between Direct-to-Consumer/ Patient Advertising of Genetic Testing and the Practice of Clinical Pharmacology

Technology is accelerating the pace of knowledge generation

Present and Future Consequences of Consumer Experiences with Genetic Testing

e value of information derived from genetic testing of polygenetic disease is likely to improve rapidly over the next decade. Currently, however, there is limited ability to predict the risk of diseases based on genetic pro les and genomic expression patterns. It is important that consumers realize that issues regarding scienti c quality and reproducibility of genetic and genomic tests must be resolved; consequently, the quality is not uniformly there yet [6] Consumers who are not prepared for the uncertainty and risk associated with genetic testing may su er as a result [7] Furthermore, at a population level, these collective experiences may give future genetic testing a poor reputation, and it consequently may not be trusted by consumers. is negative branding can be an unintended marketing consequence of premature promotion and uptake of DTC/P genetic testing. is outcome could deter the future utilization of pharmacogenetic testing to inform choices about medication use, which is a long awaited scienti c advance in our discipline. To prepare consumers/patients who are considering taking action in response to DTC/P promotion and advertisement of genetic testing [8] clinical pharmacologists could convey the following cautionary advice: Verify, in consultation with a knowledgeable and trusted professional, the information presented in DTC/P advertisements of genetic testing. What is the population at risk for the disease that is the focus of the advertisement, and what percentage of individuals with that disease actually has a strong genetic component to the disease's expression? Seek professional advice. If genetic testing is being recommended by a health care professional not trained in genetics, seek genetic counseling from a trusted source prior to making a decision about having a genetic test. Recognize the scienti c limitations of each test. With a few exceptions, genetic testing currently being advertised directly to consumers provides information that is not readily translatable to the type of knowledge needed to inform therapeutic decisions. Realize that many companies that sell DTC genetic testing services do not provide interpretation of test results. Pre- and posttest counseling and result interpretation must be sought by the consumer. Clinical pharmacologists can assist with genetic testing that is pharmacotherapy related and thereby add value to the consumer experience for this type of genetic test. Other genetic test results can be triaged to appropriate clinicians for interpretation and communication of risk assessment.

Conclusion

Pharmacogenetics and pharmacogenomics are expanding the frontiers of health professions. Clinical pharmacology will have a voice in how the evolving science translates not only into clinical trials and patient care but also into regulations involving the promotion and advertising of all genetic tests. Clinical pharmacologists can help ensure that realistic expectations of genetic and pharmacogenetic/genomic tests are communicated, thereby mitigating psychological, social, and medical risks.

References

1. Bertino JS Jr, Greenberg HE, Reed MD; American College of Clinical Pharmacology (2007) American College of Clinical Pharmacology position statement on the use of microdosing in the drug development process. J Clin Pharmacol 47: 418-422.
2. Genetics and Public Policy Center
3. Kaye J (2008) The regulation of direct-to-consumer genetic tests. Hum Mol Genet 17: R180-183.
4. Smith SH (2009)"The physician's hand": trends in the evolution of the apothecary and his art across Europe (1500-1700). Nuncius 24: 97-125.
5. US Department of Health and Human Services (DHHS) (1999) Guidance for Industry: Consumer-Directed Broadcast Advertisements.
6. Hudson KL, Murphy JA, Kaufman DJ, Javitt GH, Katsanis SH (2006) Oversight of US genetic testing laboratories. Nat Biotechnol 24: 1083-1090.
7. Clayton EW (2003) Ethical, legal, and social implications of genomic medicine. N Engl J Med 349: 562-569.
8. Federal Trade Commission. (2006) At-Home Genetic Tests: A Healthy Dose of Skepticism May Be the Best Prescription Washington, DC: Bureau of Consumer Protection Division of Consumer and Business Education.