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Direct-to-Consumer/Patient Advertising of Genetic Testing: A Position Statement of the American College of Clinical Pharmacology

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Scientific and technologic advancements influence decision making by drug discovery and development scientists, clinicians, and regulators. The American College of Clinical Pharmacology (ACCP) uses these scientific milestones to communicate its understanding of the potential impact of the new technology and regulatory change that may accompany it.

Position papers are one means of educating our members and the communities in which they work. These formal statements strive to convey the collective professional judgment of many clinical pharmacologists on technology or policy issues. An example is the *Journal of Clinical Pharmacology* scientific paper that evaluated the information value of microdosing/accelerator mass spectrometry studies for early drug development decisions.¹

This position paper's focus—advertising of genetic testing services directly to the consumer/patient—has

been thrust into the headlines by action taken by state health departments in California and New York against certain private testing companies. The topic is compelling to clinical pharmacologists because the response of consumers to such advertising can have both immediate and long-term effects on public health and the future adoption of pharmacogenetic/genomic testing.

THE LINK BETWEEN DIRECT-TO-CONSUMER/PATIENT ADVERTISING OF GENETIC TESTING AND THE PRACTICE OF CLINICAL PHARMACOLOGY

Technology is accelerating the pace of knowledge generation in genetics and genomics and the availability of testing for heritable mutations and variations in genomic expression patterns. Clinical pharmacologists work at the interface of this technology and regulations that are intended to ensure integrity and validity of the information generated.

Several organizations concerned with genetics and public policy have formally communicated their positions about genetic testing services and promotion directly to the consumer audience rather than through clinicians. A common area of concern that many clinical pharmacologists share is the deficiency in regulation in 2 areas: the genetic laboratory tests and the print advertisements and Internet Web sites promoting genetic testing services directly to the consumer/patient.

Regulations are especially critical when test results are applied to medical decisions. The main types of genetic tests that are currently regulated by

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the Food and Drug Administration (FDA) are test kits or systems intended for use in multiple laboratories. In contrast, the vast majority of genetic tests are developed internally by a clinical laboratory company and do not undergo premarket review that is routine for *in vitro* diagnostic test products classified as medical devices. Even when genetic tests are developed in laboratories that comply with the Clinical Laboratory Improvement Amendment (CLIA) of 1988, this regulation does not address the clinical validity of a particular test.²

The absence of a firm and uniform regulatory environment^{2,3} is partly due to the fact that regulatory policy makers have been challenged by the rapid pace of the technology. This environment may increase the chance that some promotion and advertising may obfuscate risk taken on by a consumer who pursues genetic testing. The chance for harm is particularly likely when the consumer does not work closely with his or her clinician familiar with genetics principles or a clinical geneticist or genetic counselor.

After more than a decade of direct-to-consumer/patient (DTC/P) advertising of prescription medications in the United States, there is defined oversight of that promotional process. Empowered by the US Congress to protect public health, federal agencies shape drug advertising practices through published regulatory code.⁴ The FDA's Division of Drug Marketing, Advertising, and Communications (DDMAC) communicates policy⁵ and actively monitors compliance with regulations for advertising and marketing. Government regulatory agencies are complemented by self-policing authorities within the industry that creates consumer-focused advertising about disease states and medications. A comparable oversight system is not currently in place for consumer-directed advertising of genetic testing. Given the rate of development of genetic testing and its widespread availability and accessibility by the public, the establishment of effective governmental oversight needs to be undertaken soon.

Pharmacogenetic testing, which is one type of genetic testing, evaluates metabolic enzyme and drug transporter gene variants and is contributing to the understanding of individual variation in the action of drugs in the body. Clinical pharmacologists interpret tests designed to predict which patients are likely to respond favorably to a medication and which patients are at increased risk for serious toxicity. Clinical pharmacologists recognize when testing may aid dosage selection. In initiating warfarin therapy, for example, determination of

genetic variation of both the target, vitamin K epoxide reductase complex 1 (VKOR C1), and the cytochrome P450 metabolizing enzyme CYP 2C9 may optimize anticoagulation in less time and with a lower risk of bleeding for the patient than without this genetic testing. This type of knowledge complements that of other health care providers, particularly genetic counselors, and together can guide health care decisions (eg, whether to undergo a medical procedure or take a particular drug or drug dosage). Finally, clinical pharmacologists leverage their understanding of drug development to foster appropriate inclusion of pharmacogenetic testing into clinical trials and correct interpretation of the results they generate.

The above-mentioned examples are significant translational milestones in integrating pharmacogenetic testing into research and clinical practice. This success may be short-lived, however, if poor consumer experience stigmatizes the genetic testing field or if an inequitable regulatory policy regarding laboratory-developed tests stifles innovation in the creation of validated genetic tests.

PRESENT AND FUTURE CONSEQUENCES OF CONSUMER EXPERIENCES WITH GENETIC TESTING

The 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 profiles and genomic expression patterns. It is important that consumers realize that issues regarding scientific 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 suffer 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. This negative branding can be an unintended marketing consequence of premature promotion and uptake of DTC/P genetic testing. This outcome could deter the future utilization of pharmacogenetic testing to inform choices about medication use, which is a long-awaited scientific 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 scientific 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.

CONCLUDING REMARKS

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.

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