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# Critical appraisal of the private genetic and pharmacogenomic testing environment in Greece

**Aim:** In the postgenomic era, we are witnessing rapid progress in the identification of the molecular basis of human inherited disorders and the elucidation of genotype–phenotype relationships. The rate of progress has been driven not only by the determination and ongoing decipherment of the human genome sequence but also by the advent of new technological developments that have dramatically reduced the costs of genetic analysis. As a consequence, a considerable number of genetic testing centers have emerged, both in Europe and the USA, which together offer a plethora of different genetic tests. **Methods:** We have performed a nationwide survey of 18 private genetic testing laboratories in Greece in order to acquire a better understanding of the genetic testing services that these centers provide, specifically the types of genetic test offered, the target groups, marketing channels, costs of analysis and accreditation. **Results:** Molecular genetic and cytogenetic testing were found to be the predominant types of genetic testing services offered although there is an increasing demand for pharmacogenomic testing. The main target group for private genetic testing laboratories is the physicians who are approached via the internet, through personal contacts from sales representatives and at scientific conferences. Genetic testing costs are fairly low in Greece. Although the majority of private genetic laboratories either employ or collaborate with a genetic counselor, few of them are accredited for the provision of genetic testing services. **Conclusion:** This study constitutes the basis for a critical appraisal of the private genetic testing environment in Greece and provides a model for replication in other European countries.

**KEYWORDS:** cytogenetics ■ genetic testing ■ Greece ■ molecular genetics ■ pharmacogenomics ■ physicians ■ private laboratories

In recent years, significant advances have been made in our understanding of the genetic basis of inherited disorders and the correlations between mutant genotype and clinical phenotype, both for monogenic and multifactorial conditions [1,2]. These advances, in conjunction with the advent of high-throughput genetic analysis and deep resequencing, have served to reshape the field of modern medical practice [3] and are reflected in the rapid development of the genetic testing industry [4,5]. Nowadays, there are a wide variety of public entities and private companies that offer a broad range of antenatal and postnatal molecular genetic testing services for monogenic and multigene disorders, classical and molecular cytogenetics analysis for chromosomal rearrangements, pharmacogenomic testing and even predictive genomics for genetic disorders. In addition, many laboratories also offer molecular genetic testing services in microbiology and virology. At the same time, genetic testing services are becoming more affordable and therefore we can already envisage genome resequencing for as little as US\$1000 per individual [6]. However, the rapid expansion of the genetic testing industry has not come without its

problems. In particular, some laboratories still offer genetic analysis services using in-house ('homebrew') kits rather than quality-controlled and certified assays. In addition, many laboratories test results are not invariably interpreted by a qualified professional (e.g., a genetic counselor), whereas other laboratories are not yet accredited for the provision of genetic testing services [7]. Moreover, it transpires that, in several cases, genetic analysis is routinely conducted without obtaining informed consent from those persons requesting the test. This raises serious ethical concerns in relation to the preservation of the anonymity of the individuals tested [8], the fate of their genetic material and, most importantly, the safeguarding of test results in order to avoid genetic stigmatization [9].

The landscape of private genetic testing services is still poorly developed in many parts of Europe and the USA, a direct consequence of the lack of any proper regulatory framework. Hence, a number of different ethical issues often arise. EuroGenTest [101] has recently attempted to plug this gap by initiating a drive to harmonize genetic testing services in Europe. In parallel, OrphaNet [102] has attempted to database the

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plethora of genetic testing laboratories in Europe but these efforts have often been hampered by the lack of willingness of some laboratories to communicate the requested details of their operations. It is therefore clear that, in the emerging era of personalized genomics, the task of 'fine mapping' genetic testing services in Europe is assuming ever greater urgency.

We have initiated nationwide surveys to assess private genetic testing services currently available in Greece, not simply from the patients' and physicians' point of view but also from the test providers' standpoint. In these surveys, we have aimed to: map patients' and physicians' needs with respect to the genetic testing industry; identify regulatory deficiencies and gaps in the existing legal provision that could be rectified by appropriate legislation; and provide a model for the European-wide survey of genetic testing laboratories with the ultimate goal of harmonizing genetic testing in Europe. Here, we report the results from our initial survey of private genetic testing providers in Greece.

## Methods

This research study was conducted between March 2010 and December 2010, during which time 18 private genetic testing laboratories from various cities in Greece (TABLE 1), and comprising the bulk of the genetic testing industry in Greece, were invited to participate. The names and websites of the participating laboratories will be made available upon request.

The survey addressed issues such as: the collection of data on the types of genetic testing services provided; the laboratories' clientele; specific details of the approach to genetic testing, such as methods of DNA isolation and analysis, and accreditation; approaches to marketing; and the costs to the consumer of the genetic tests being offered. A 21-point questionnaire (SUPPLEMENTARY TABLE 1, [WWW.FUTUREMEDICINE.COM/DOI/SUPPL/10.2217/pme.11.24](http://www.futuremedicine.com/doi/suppl/10.2217/pme.11.24)) was sent

electronically to the laboratories' scientific and management personnel for self-completion, from which quantitative data were subsequently generated. Pharmacogenomic testing formed an integral part of the questionnaire, since it has gradually become an important area of personalized medicine.

A simple binary approach (no = 0, yes = 1) was employed to score the answers given. Information provided was then crosschecked from the corresponding websites, where available to ensure accuracy and consistency.

## Results

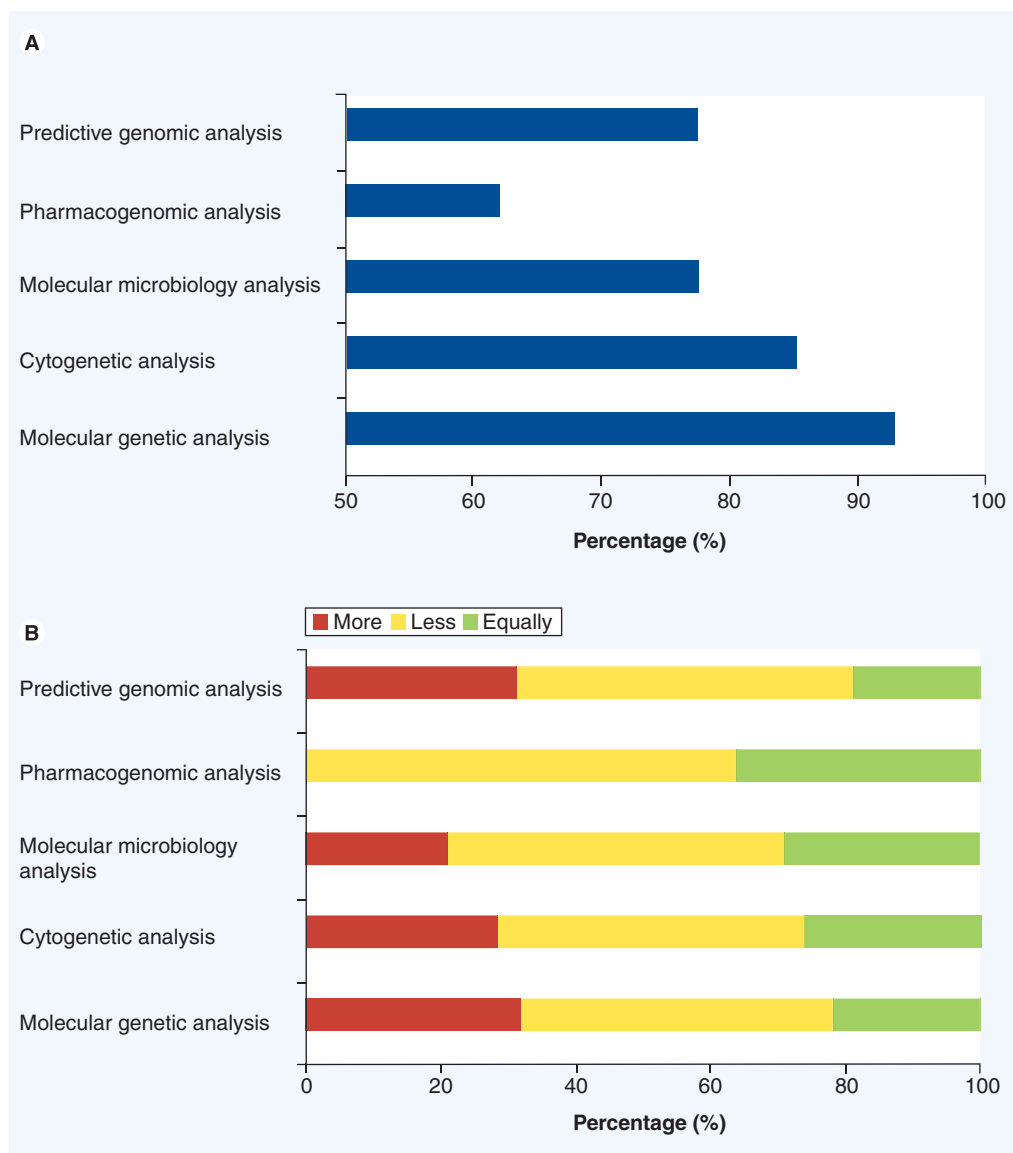
A total of 13 of the 18 private genetic testing laboratories (72.2%) responded to the questionnaire. More than three reminders had to be sent to 9 of the 13 private laboratories that responded to our survey in order to elicit a response; this situation may reflect a certain degree of reluctance on the part of commercial entities to participate in such surveys [PETERSEN MB, PERS. COMM.].

Our data indicate that most of the surveyed genetic testing laboratories (92.3%) are involved in the provision of molecular genetic analysis for inherited disorders, followed closely by classical and/or molecular cytogenetic testing (84.6%), and molecular genetic testing for microbiology and predictive genomics (76.9%; FIGURE 1A). By contrast, pharmacogenomic analysis was only offered by 8 of the 13 laboratories that completed the survey (61.5%). From this initial survey, it would appear that there is currently a greater demand for molecular genetic and predictive genomic testing services than other types of analysis (FIGURE 1B).

The questionnaire responses indicated that physicians and the general public are the main target group for 92.3% of the genetic laboratories, followed by other interested parties such as other genetic laboratories, diagnostic centers, hospitals and pharmaceutical companies (30.8%). The main specialties that the diagnostic laboratories address are obstetricians/gynecologists (92.3%), followed by pathologists (69.2%), cardiologists (69.2), psychiatrists (30.8%) and other specialties, namely oncologists, pediatricians, hematologists, urologists, neurologists and surgeons. This may not be unexpected since obstetricians and gynecologists usually order molecular genetic and, particularly, cytogenetic tests to screen for fetal malformations, particularly in cases with a family history. In addition, the physicians who order pharmacogenomic tests more frequently are psychiatrists, cardiologists and oncologists, since these are the disciplines in which pharmacogenomic

**Table 1. Locations of the private genetic laboratories from Greece invited to participate in the study.**

City	Number of laboratories		
	Invited	Responded	%
Athens	12	10	83.3
Piraeus	2	0	0
Thessaloniki	1	1	100
Patras	1	1	100
Alexandroupolis	1	0	0
Heraklion	1	1	100
Total	18	13	72.2



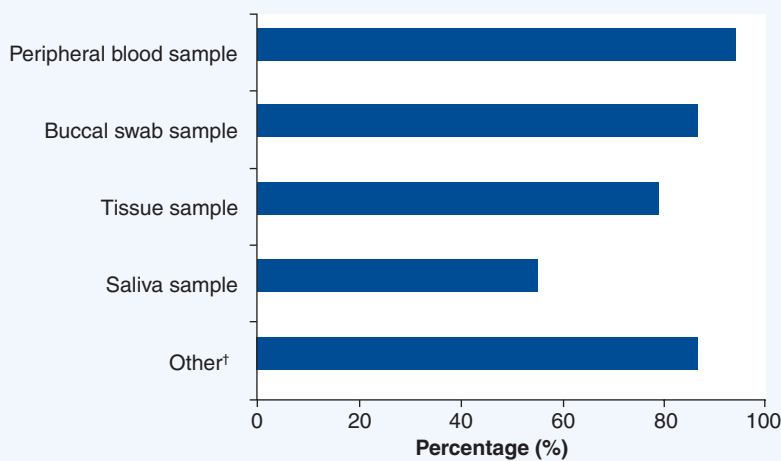
**Figure 1. Types of genetic tests offered in Greece. (A)** The various types of genetic testing analysis offered by private genetic laboratories in Greece and **(B)** their relative proportions in terms of the demand for these tests.

testing has been most widely adopted. Of course, other factors may influence the proportions of physicians ordering the genetic tests, for example the numbers of clinicians in different specialties, differential funding available to practitioners in each specialty, differences in genetics education between specialties and so on. Interestingly, in the context of paternity testing, lawyers can also be a target group for the genetic testing laboratory.

In the case of the age range of the people undergoing genetic testing, 92.3% of private genetic laboratories have clients between the ages of 35 and 60 years old, followed by people younger than 35 years old (76.9%). Perhaps unsurprisingly, people older than 60 years of age are less likely to undergo genetic testing (46.2%), most

likely owing to their lack of knowledge about the potential benefits of genetic analysis [10]. It might also be that people older than 60 years of age are less likely to require/wish genetic disease testing, as they are probably already quite knowledgeable about their existing pathologies from personal experience, and rather less likely to want paternity testing for other fairly obvious reasons. However, one would perhaps expect this group to be more likely to avail themselves of genetic testing in an oncology context.

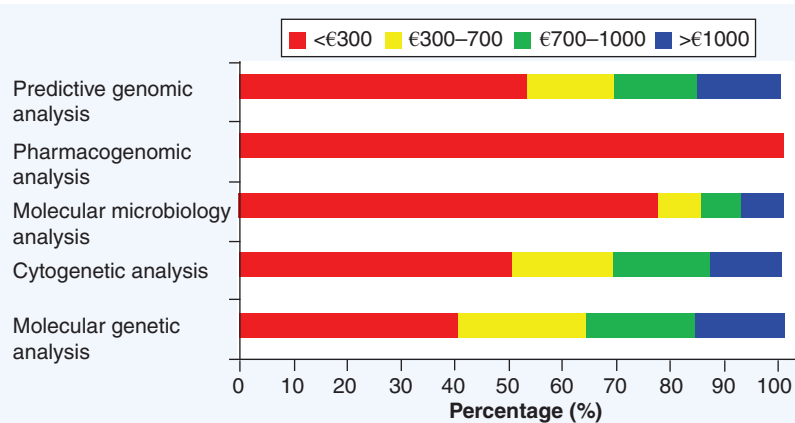
As far as the source of the genetic material is concerned, peripheral blood was found to be the most commonly used DNA source (92.3% of the surveyed laboratories), followed by buccal swab samples (84.6%), tissue samples



**Figure 2. Relative proportions of the main DNA sources used for genetic analysis.**

†Refer to text for details.

(e.g., paraffin-embedded tissue or fresh biopsies; 76.9%), saliva (53.9%) and other sources such as semen, urine and cell cultures (FIGURE 2). The choice of sample is going to be very much test-dependent, and hence, very much a function of what tests the different companies perform. For example, buccal swabs and saliva samples may be more frequently used as a DNA source for predictive genomic testing, whereas peripheral blood will be used for molecular genetic testing services. An integral part of the questionnaire was the issue of the cost to the consumer of the available tests. The majority of genetic laboratories offer genetic tests that are cheaper than €300 (FIGURE 3), whereas the number of genetic tests offered decreased with the increasing cost of the corresponding analysis (FIGURE 3 & SUPPLEMENTARY TABLE 1, [www.futuremedicine.com/doi/suppl/10.2217/pme.11.24](http://www.futuremedicine.com/doi/suppl/10.2217/pme.11.24)). All pharmacogenomic tests offered



**Figure 3. Breakdown of the costs of genetic analysis by type evaluated in this survey.**

were cheaper than €300, while in some cases the cost of the test was as low as €50 when such tests are ordered and performed in bulk.

Although the majority of private genetic testing laboratories performed genetic analysis with informed written consent from the patients (76.9%), several genetic laboratories did not fulfill this requirement, according to their responses to our survey. This finding underlines the need to make informed written consent an obligatory requirement for genetic testing in Greece but also in other European countries.

It was however encouraging that all the private genetic testing laboratories that responded to our survey had or were collaborating with a genetic counselor. Although the majority of genetic testing laboratories have an International Organization for Standardization (ISO) certificate (84.6%), and therefore may be considered accredited, very few have been certified for the provision of genetic testing services specifically (ISO-15189 and/or ISO-17025) [7], namely ISO-17025 (15.4%) and ISO-15189 (15.4%). The accreditation system in Greece follows that adopted in other European countries. The introduction of new genetic and pharmacogenomic tests occurs after consultation of the scientific literature for new research studies on genotype–phenotype correlations (76.9% of the surveyed laboratories), followed by recommendations from an internal scientific review group, to the company, scientific advisory board or scientists (69.2%), external physicians (61.5%) or advisors (38.5%).

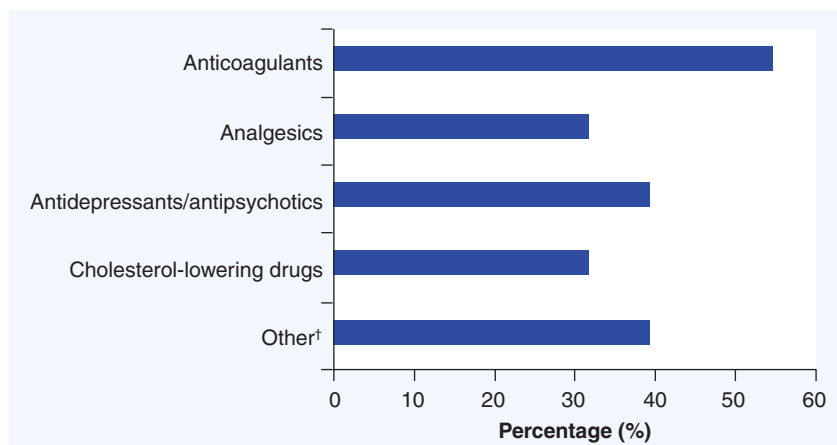
As stated above, 61.8% of the private genetic laboratories offer pharmacogenomic testing services. These tests relate mostly to anticoagulant drugs (53.9%), followed by antidepressants and antipsychotic drugs (38.5%), cholesterol lowering drugs (30.8%), oncologic drugs (15.4%) and analgesics (30.8%; FIGURE 4). Finally, we wished to understand the various marketing approaches adopted by each laboratory to attract test samples. According to our survey, the laboratory's own website constituted the most frequently used means to inform both the general public and physicians about new genetic and pharmacogenomic tests being offered (both 92.3%). Other means of communication employed by the genetic laboratories were contact with physicians at scientific conferences (69.2%) and direct contact with sales representatives (69.2%), whilst only 23.1% of the genetic laboratories organized educational seminars to inform physicians about their services. Despite this, 46.2% of the genetic laboratories had participated as sponsors and 30.8% as exhibitors in a recent 2010 Greek medical or genetics-related

conference, in which physicians mostly participate. By contrast, 61.5% of the genetic laboratories inform the general public of their available genetic and pharmacogenomic tests via custom-produced advertising material (e.g., leaflets and brochures that are mailed to them directly, whereas only 23.1% employed advertisements in newspapers or magazines. According to the survey, none of the respondent genetic laboratories uses a call center to communicate their services directly to the general public by making unsolicited calls to tout for business. However, we are aware that at least one of the laboratories that failed to respond to our questionnaire uses this approach as part of its public outreach strategy. In addition, buccal swab sampling kits for genetic tests are sold over the counter in at least one chain of pharmacies in Greece, whereas other pharmacies provide the same sampling kit upon request.

## Discussion

The rapid pace of development in the field of human genomic technologies has led to an exponential increase in the number of available genetic tests and a decrease in the relative cost of each genetic analysis. As a result, genetic testing services have become readily available to patients and the general public alike, whether to assess the risk of developing a life-threatening inherited disorder or to predict the efficacy of (or toxicity to) a specific drug. Indeed, it is estimated that more than 700,000 genetic tests are performed in Europe on an annual basis [11], and this figure is expected to grow rapidly over the next few years. Although the number of public and private genetic testing laboratories continues to grow, little is known about the general landscape in which genetic testing services operate in many countries. Indeed, in many European countries, there are gaps in legislation covering genetic testing [103], and hence the different parties involved are not fully protected from unethical practices [12]. In Europe, there are significant differences between individual countries as far as genetic testing services are concerned. The EuroGenTest Network [101] and EuroGenGuide [104] represent some of the efforts that have been attempting not only to harmonize genetic testing services across Europe but also to provide guidance on genetic testing/analysis for patients and physicians.

In a Greek context, the first genetics units appeared in Athens in the early 1960s and since 2003, at which time only five private genetic laboratories offered (a range of) genetic services in Greece, their number has increased significantly. Recently, we initiated a major nationwide survey



**Figure 4. Relative proportions of the main types of drugs for which pharmacogenomic tests are offered by private genetic laboratories.**  
†Refer to text for details.

to try to understand the context of private genetic testing services in Greece and to explore how both the general public and physicians perceive genetics and genetic testing services. Such an analysis has not previously been performed and it was designed to address key aspects of genetic analysis such as ethics and education as well as insurance and confidentiality issues. In addition, our survey paid particular attention to pharmacogenomic testing since this emerging discipline is anticipated to have a central role in translational medicine.

Our results from surveying the provision of genetic testing services from private laboratories indicate that, at present, demand leans towards molecular genetic and cytogenetic testing, following many years of successful application of these approaches. Interestingly, pharmacogenomic testing is currently the least popular among patients, probably because this is a relatively new field and people are less aware of the potential benefits of this type of test. Usually, patients are more interested in, and informed about, their own susceptibility to disease than they are about potential adverse drug reactions or interindividual differences in drug metabolism and disposition, and the same may well be true for the attending physicians. Ironically, modulating or even avoiding a particular drug treatment is relatively straightforward but it is not necessarily so easy to avoid the consequences of an innate susceptibility to disease. Thus, in the longer term, it may well be that pharmacogenomic testing will deliver the most in terms of clinical benefit to the patient and thus will be more widely adopted in a clinical setting. According to the views of certain laboratories who offer this service, pharmaceutical companies in Greece attempt to discourage physicians from recommending

pharmacogenomic testing, since this will tend to reduce the pharmaceutical companies' profit margins. The argument that they deploy is that the pharmacogenomic test costs significantly more than simply trying out the drug in question. Also, in some cases, for example, the use of vitamin K antagonists, certain recommendations stand against the use of pharmacogenomics [13], even though the US FDA in 2010 established a *CYP2C9* and *VKORC1* genotype-based dose scheme for warfarin. Given the recent emergence of this field, pharmacogenomic tests currently tend to be a low priority for customers of genetic testing laboratories, a conclusion deduced from the number of pharmacogenomic tests offered by these laboratories (FIGURE 1). This is however likely to change over time as a consequence of integrating pharmacogenomics into mainstream medical practice.

Another interesting finding is the nature of the customer target group of private genetic testing laboratories, who are primarily physicians, in particular gynecologists and to a lesser extent pathologists, cardiologists, oncologists and psychiatrists. However, the vast majority of genetic laboratories (92.3%) also receive test requests directly from patients. In this latter case, the presence of a qualified genetic counselor is required to accurately and reliably communicate the test result to the patient who requested the test. Unfortunately, this is only a qualitative result since the design of our survey did not allow us to assess the proportion of the genetic tests that come from patient self-referral, as distinct from those referred by medical practitioners. According to the laboratory personnel, physicians that refer patients to them for testing are not in a position to explain the test result, owing to the lack of the appropriate education and training. This finding concurs with the results obtained from the physicians' survey [10], where a significant proportion of physicians (particularly the older physicians) display a remarkable lack of knowledge of genetics. This can be also deduced from the fact that physicians and the general public generally tend to prefer peripheral blood as the DNA source for genetic tests, perhaps because they feel that this approach to sampling and DNA isolation somehow has a more solid scientific basis as compared with the other DNA sources.

According to the laboratory personnel questioned, the younger new generation physicians understand genetics much better and thus are not only in a better position to explain test results but are also eager to encourage their patients to undergo genetic testing in the first place. We must be aware that it has only been relatively

recently that molecular biology and genetics has been incorporated into university curricula as an integral part of medical, pharmacy and nursing studies at undergraduate and graduate level.

Another interesting finding from the genetic laboratories survey is that the means of communication with their target group is primarily via the company website (92.3%, both for physicians and patients), followed by advertising, scientific conferences and visits to physicians from sales representatives. The companies who responded to our survey indicated that they do not use call centers to make unsolicited calls to the general public to tout for business. However, the authors are aware of at least two private genetic laboratories in Athens who have either used this approach in the past or are currently using this approach in order to attract their clientele. We believe that this approach is wholly unethical since the general public is most unlikely to acquire a detailed understanding of the pros and cons of taking a particular genetic test by these means [14]. Indeed, even if the 'worried well' are not actually misled by the company's sales procedures, they will most probably be unclear as to how they might benefit from the genetic test.

One Greek pharmacy group has achieved a degree of notoriety by promoting genetic tests and selling DNA sampling kits to the public over the counter while other pharmacies are generally willing to order these sampling kits upon request. We have made enquiries with several pharmacies about the demand for these kits but it would appear that the demand is currently very low. Again, this finding concurs with the results from our general public survey [10], which have indicated that only a small fraction of the general public would prefer a pharmacist to recommend a genetic test rather than a clinician. It is noteworthy that the FDA has banned the selling of direct-access genetic tests over the counter in pharmacies, considering them medical devices that require proper regulation [105].

The Hellenic Association of Medical Geneticists ([106] content in Greek) have recently published a warning about direct-access testing services being offered by Greek private genetic laboratories using call centers, stressing that these are highly specialized tests whose benefits and results cannot possibly be communicated by phone, and by people who have not received the appropriate training. The Society has also stressed that if there were proper regulatory and legal frameworks in place, they would prevent such practices in what is still fortunately a fairly small number of genetic laboratories. Costwise,

the provision of genetic testing services is reasonably cheap with the majority of genetic tests costing less than €300, and in certain cases below €50. Bearing in mind the continuously falling costs of genetic analyses, the current profit margins of these laboratories are likely to be still high, and thus there is considerable room for price reductions in the future (at least in a truly competitive market).

It seems quite evident that the provision of genetic testing services in Greece has not yet benefited from any central planning, nor has it yet acquired an appropriate regulatory framework. This conclusion can be drawn not only from certain outcomes of the present study (e.g., lack of proper accreditation) but also from various other elements, such as the absence of legislation or directives for the practice of genetics or the genetics specialty. This of course may resemble the situation pertaining in other European countries, although for some of them (such as the UK, Germany, the Netherlands and several others), genetic testing is well organized. There are no professional guidelines concerning quality assessment of genetic services in Greece, although recently, more optimistically, many molecular genetic laboratories have joined quality assessment schemes for genetic disorders organized by the European Molecular Genetics Quality Network [15,107]. Despite this, very few Greek genetic laboratories have been accredited with an ISO-15189 or ISO-17025, while other genetic

laboratories are accredited with an ISO-9001 or equivalent, and hence are not properly certified for genetic testing.

In essence, our study constitutes the basis for a critical appraisal of the private genetic testing environment in Greece and provides a model for replication in other European countries to assess the landscape of genetic testing services.

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*No writing assistance was utilized in the production of this manuscript.*

### Ethical conduct of research

*The authors state that they have obtained appropriate institutional review board approval or have followed the principles outlined in the Declaration of Helsinki for all human or animal experimental investigations. In addition, for investigations involving human subjects, informed consent has been obtained from the participants involved.*

### Executive summary

- The landscape of private genetic testing services is poorly developed in many European countries as well as in the USA.
- We have performed a survey of 18 private genetic testing laboratories located in Athens and various other cities in Greece in order to obtain a better understanding of the genetic testing services that these centers provide.
- Our questionnaire included 22 questions on various aspects of genetic testing, such as the types of genetic test offered by these private laboratories, their target clientele and the marketing channels used to approach them, the cost of the analyses and laboratory accreditation.
- A total of 13 of the 18 private genetic testing laboratories responded to our questionnaire and analysis of their responses indicated that although molecular genetic and cytogenetic testing tend to predominate, the demand for pharmacogenomic testing is steadily growing.
- In Greece, physicians comprise the main target group for private genetic testing laboratories. Generally, they tend to be approached via the internet, through personal contact from sales representatives or at scientific conferences.
- Although the costs of genetic testing are fairly low in Greece, most genetic laboratories either employ, or collaborate with, a genetic counselor. However, few laboratories appear to be properly accredited for the provision of genetic testing services.
- Our study constitutes a critical appraisal of the private genetic testing environment in Greece and provides a model for replication in other European countries.

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