



# REGULATING DIRECT-TO-CONSUMER ADVERTISING OF GENETIC TESTS: LEGITIMATE OR NOT?

## DIRECT-TO-CONSUMER (DTC) ADVERTISING OF GENETIC TESTS IN THE WEB 2.0 ERA

Additional tools available: Facebook, Twitter, blogs, Youtube channels, promotional emails etc  
→ regulation of this field is complicated.

## RAISED QUESTIONS

Health-related genetic tests = medical devices conveying complex information, often associated with medical and psychological risks, potentially targeting a vulnerable part of the population

- Can DTC advertising educate and inform consumers when their main purpose is to increase the sale of the products advertised?
- Should advertising of genetic tests be regulated as common consumer goods?

## REGARDING THE CURRENT REGULATORY LANDSCAPE

No European laws specifically regulating this matter → fragmented regulatory landscape

- EU Directives:
  - Directive 2005/29/EC on unfair commercial practices
  - Directive 2006/114/EC concerning misleading and comparative advertising
  - Directive 98/79/EC on in vitro diagnostic medical devices
- National legislation
  - In most European countries general laws on advertising and consumer protection for commercial goods and services apply
  - Spain bans DTC advertising of genetic tests with the Royal Decree 1662/2000

## >> EUROPEAN PARLIAMENT PROPOSES BAN

The European Parliament has suggested in its version of the proposed regulation for in vitro diagnostic medical devices that all genetic tests with a direct or indirect medical purpose should be classified as prescription only medical devices, the DTC advertising of which should be forbidden.

## THAT SEEMS TO BE OVERLY RESTRICTIVE

Strict legislation ensuring the accuracy of promotional claims necessary for all genetic tests, but:

- What is direct or indirect medical purpose?
- One size fits all or balance risks and benefits of different categories of tests?

Different levels of protection according to the risks associated with them may be a more appropriate response

## CONTACT US TO FIND OUT MORE

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