International Journal of Impotence Research (1998) 10, 105–109
 0955-9930/98 $12.00
http://www.stockton-press.co.uk/ijir

Editor's note
The Society for the Study of Impotence meeting at the 1997 American Urological Association's meeting

One of the new features that we want to add to the IJIR is the publication of lectures delivered at the one-day regional meetings of ISIR so that the content would be available to our entire membership. The Society for the Study of Impotence (SSI) is the American Urological Association's society whose members have primary interest in the study and treatment of sexual dysfunction. Its members are a major component of the American branch of the International Society for Impotence Research.

The following are either synopses or full manuscripts of most of the lectures given at the 1997 annual meeting held in April 1997 in New Orleans, Louisiana. Some of the topics have a common relevance (for example, Peyronie's disease, gene therapy). Some, such as Sondra Mills' discussion of the American government–practitioner interaction are more regionally focused but the concept has global relevance.

A Melman
Editor

'Treatment mills' under the Federal Trade Commission Act

SL Mills

*Senior Attorney, Federal Trade Commission, Washington, D.C.**

This paper is based on a presentation made by the author at the meeting of the American Urological Association's Society for the Study of Impotence on April 12, 1997. The author addresses the general applicability of the Federal Trade Commission Act to advertising by so-called impotence 'treatment mills,' focusing in particular on the Federal Trade Commission's case in the matter of *Genetus Alexandria, Inc., et al.*

Keywords: treatment mills; advertising by professionals; Federal Trade Commission Act

Introduction

During the winter of 1994, some of the men in my office began talking about advertisements they had heard on a popular sports radio station in the Washington, DC area for an impotence treatment clinic known as 'Genetus.' Something about the ads just did not ring true, they said. The promises just sounded too iron-clad. I had done several health care fraud cases, so our Division head suggested that I look into it. All of us knew a lot about questionable advertising practices, but none of us knew anything about the treatment of impotence. Consequently, my first challenge was to attain a sufficient working knowledge of the relevant medical issues to allow me, as an attorney for the government, to evaluate the veracity of advertising claims regarding impotence treatments. During this period, some of you present here today shared your knowledge and expertise with me and other members of the Commission's staff. I am now delighted to have the chance to return the favor. It is in fact an honor to me to be included here among these scholarly presentations, along with those of you whose articles and treatises I poured over, not so very long ago.

Your President-elect, Dr A Melman, has asked me to offer you some insight into the federal government's perspective on how practicing urologists should respond to the establishment of specialty

Correspondence: SL Mills Esq., Division of Services Industry Practices, United States of America, Federal Trade Commission, Washington DC 20580, USA.

*The views expressed in this paper are exclusively those of the author and do not represent the views of the Federal Trade Commission, of any Commissioner, or of any other member of the Commission's staff.

urologic clinics that are run by non-urologists. As I understand the problem, you are concerned about the proliferation of impotence 'treatment mills' that attract a high volume of patients despite the fact that they may not offer a commensurately high quality of medical care. As a consequence, you are concerned that patients may not be receiving what you believe to be the best care available. You do not want patients, or yourselves, to be victims of the 'treatment mill' phenomenon. I gather that you want to know how to reach these patients—in effect, how to compete in this environment.

As I explained to Dr Melman when I accepted his invitation, however, I cannot advise you as to how you should respond. By now, I suspect that most of you have had sufficient dealings with lawyers, the law, and government to be able to appreciate what one very wise jurist meant when he wryly observed that the law is not among the healing arts. By its nature, the law proscribes conduct. Rarely does it prescribe a course of action in the same way that you prescribe treatments. Moreover, I am not sufficiently close to your situation to know what kinds of responses you have already entertained and to comment on the legal implications of those as possible choices.

I should also make it clear that I am not a policy-maker or a presidential appointee. Consequently, I cannot opine on what positions the government may or should take on various issues today or in the future. Rather, I am a senior attorney at the Federal Trade Commission. What that means is that I am a prosecutor who principally handles specific cases. As such, I see myself as doing something akin to what you do—treating patients—in my case, trying to find a remedy for consumers who have been injured by false and misleading claims.

Having made these appropriate lawyerly disclosures and disclaimers, let me say that what I can do is tell you something about the Federal Trade Commission and about some of the advertising practices that have, over the years, been examined by the FTC. While the law may not itself be among the healing arts, I do believe that the FTC's heart is in the right place. I am confident that well-intentioned medical professionals can navigate the legal waters and find ways of making sure that the healing arts themselves remain among the healing arts.

The FTC's role in regulating advertising by professionals

The FTC's present role is best viewed in the larger context of developments in the law governing advertising by physicians and other professionals. Some 20 years ago, the United States Supreme Court examined certain laws restricting advertising by professionals. In two separate cases involving advertising by pharmacists and lawyers, the Supreme Court held that the Virginia Pharmacy Board and the State Bar of Arizona had both unconstitutionally impinged upon the First Amendment's guarantee of free speech when they prohibited their members from certain truthful advertising.[1]

In these and other cases, the Court held that 'commercial speech' is protected by the First Amendment, noting that truthful information about the availability of professional services is important to assuring informed and reliable decision-making by the consumers who purchase them.[2] While advertising by professionals can be regulated to serve the public interest, it cannot be barred altogether. The Court expressly rejected arguments that advertising by professionals should be prohibited because it might undermine professionalism, promote commercialization, or cause overhead costs to increase.[3] Similarly, the Court rejected the contention that such advertising is inherently misleading because the content and quality of professional services are so individualized that consumers will be unable to make an informed comparison on the basis of advertisements.[4] The Court made it clear, however, that professional advertising is quite properly regulated to guard against false, deceptive or misleading claims.[5]

These rulings have had a substantial impact on the work of the Federal Trade Commission. The Federal Trade Commission Act broadly prohibits, on the one hand, 'unfair and deceptive acts and practices' and, on the other hand, 'unfair methods of competition.'[6] Since the late 1970s, the Commission has approached advertising by physicians and other professionals from these two perspectives. The FTC's Bureau of Competition has examined restrictions on physician advertising from an antitrust perspective, culminating in findings by the Commission and the courts that physician groups had restrained competition among physicians by suppressing truthful advertising and other forms of solicitation of patients.[7] The Commission's Bureau of Consumer Protection, where I work, has examined advertising by doctors and other medical professionals chiefly from the standpoint of whether it is false, misleading, or deceptive.

The office in which I work (the Division of Service Industry Practices) has brought roughly 35 cases involving the advertising and sale of medical services. Because these cases inherently touch on issues of the quality of care in highly technical medical areas, it is a field in which we tread very lightly. The first case we brought in this area was one against a Dr C Jacobson, an Alexandria, Virginia physician whose bogus fertility treatments earned him considerable notoriety and, eventually, a prison sentence as well.[8] I have handled cases involving supposed quick weight loss clinics, varicose vein treatments, and cosmetic surgery procedures, among others. Some of these cases are brought in federal

court; other are conducted pursuant to the FTC's administrative procedures. To me, these are exceptionally interesting and satisfying cases. This is because the consumer injury often involves not just monetary losses, but lost time in seeking appropriate treatment options and possibly even physical injuries. One case like this was the case against the Genetus impotence treatment clinics.[9]

The FTC's case against Genetus Alexandria, Inc.

A review of the practices of the Genetus clinics gives context to this notion of an 'impotence mill' and brings into clearer focus the central concern you have raised. The Genetus corporation was owned and operated by two individuals, George Oprean and his wife Linda, neither of whom was a physician. The clinics employed, as independent contractors, various physicians, none of whom was present in the clinics for more than one or two days each week. Some of them were urologists; others were not. One of the clinics was located in Alexandria, Virginia; another was in Baltimore, Maryland.

Genetus attracted patients by its advertising campaign, which consisted primarily of radio advertisements aired on stations that targeted sports fans and ethnic and racial minorities. These advertisements promised that each patient would be medically tested, evaluated, and treated and that he would be fully functional again on his very first visit. The ads further claimed that each patient's condition was 100% treatable and that the treatments would permanently arrest the patient's impotence.[10] Promotional literature mailed to prospective patients represented that the drug used in the treatments, Prostaglandin E-1, 'has no side effects or contraindications' and 'is the safest drug that can be used'.[11]

I initially concluded that this case only presented issues of misleading promises about safety and efficacy. A more thorough investigation proved me wrong. In fact, Genetus was really an insurance fraud scheme. The advertising lured patients into a clinic where many of them never saw a doctor. As the FTC alleged in its complaint, many patients were treated by Linda Oprean, who was at that time a registered nurse. Ms Oprean falsified her nursing license and held herself out to the physicians who worked at the clinics as a nurse practitioner who was, under Virginia law, authorized to perform certain medical acts pursuant to a treatment protocol.[12] Following a brief examination, during which a standard battery of laboratory tests was routinely ordered, each patient received a test injection of Prostaglandin E1. A day or two later, the patient returned to the clinic to report the results of his test injection. At that time, he was given a prescription for Prostaglandin E1 or a Tri-mix solution consisting of Prostaglandin E1, Papaverine, and Phentolamine, and sold a large quantity of the drug at grossly inflated prices.

Thus, contrary to the express promises made by Genetus, many patients were never examined or treated by a physician, and many never received a medical diagnosis of, or treatment for, the underlying cause of their impotence. Nevertheless, Genetus billed insurance companies and individual patients alike top dollar for the services of a physician. Although Genetus represented to patients that their insurance would, in most cases, cover the majority of the costs of the treatments, insurers frequently rejected claims for goods and services billed by Genetus. According to the Commission's complaint, insurers refused to pay many claims because medical tests and laboratory procedures billed by Genetus had not actually been performed, medical services had been rendered by persons who were not properly licensed to perform them, or the claims had been signed by Linda Oprean without the physician's knowledge or permission. Moreover, the amounts Genetus charged for some goods and services bore no reasonable relationship to their costs and substantially exceeded the amounts insurers had agreed to pay. Consequently, patients were left responsible for paying most or all of the costs billed by Genetus.

Although Genetus charged patients for a medical diagnosis and treatment, patients who experienced complications found themselves on their own. At least some of the doctors who worked at Genetus viewed themselves as providing only a specialty service and denied having any on-going doctor-patient relationship with the patients. Emergencies resulting from priapisms were simply not their problem, and some patients suffered greatly as a result.[13]

The FTC challenged both the false advertising claims and the fraudulent insurance and billing practices of the Genetus clinics. Although the Commission endeavored to secure refunds for the patients, it appeared that the proceeds had been dissipated. The United States Attorney in Alexandria, Virginia subsequently charged George Oprean with mail fraud and tax evasion in connection with his operation of the Genetus corporation, and Mr. Oprean pled guilty to these charges.[14]

I trust that most of you would conclude that Genetus was a 'treatment mill,' but not because of the charlatanism of its staff or the insurance fraud the clinics committed. Rather, I suspect you would characterize it as a 'mill' for reasons like these:

(1) the clinics were free-standing clinics, not affiliated with other medical facilities;
(2) the clinics were not owned or controlled by

doctors, much less by specialists trained in urology;
(3) all patients were treated in ritualistic fashion with injection therapy, without regard to their diagnosis, and no other treatment regimen was provided;
(4) an insufficient effort was made to diagnose and treat the underlying cause of each patient's impotence, or to take broader responsibility for the patient's well-being;
(5) patients were brought into the clinics by advertising, not through referrals from other physicians who had already treated the medical condition triggering the impotence and had made at least some preliminary determination about whether additional treatment was appropriate or warranted.

These characteristics may well not be conducive to the highest quality of medical care. However, absent specific advertising claims promising something other than what is delivered, 'treatment mills' with these characteristics do not *per se* violate the FTC Act. Various state agencies do regulate some of the conduct of clinics like these, but that varies from state to state. By and large, practicing second-rate medicine may only expose such a mill to malpractice liability, and then only after the damage has been done. So what are you to do?

Two possible responses: advertising and public education

Physicians seeking to attract patients away from 'treatment mills' can, of course, advertise their own services. Many of you apparently choose not to advertise, and you are free to make this choice. No law requires you to advertise.

If you do choose to advertise, however, I personally do not believe that it is very difficult to promote health care services that are of a high quality. You need only be certain that the claims you make are truthful. The claims must also not be deceptive: that is, they should not present truthful information in a misleading light. An example of deception goes something like this: Dr Jones, a dermatologist trained at universities on the West Coast, has attended a weekend seminar in liposuction, offered in a seminar room at a hotel located in Cambridge, Massachusetts. When asked about his qualifications to perform liposuction, he tells his patients that he studied in Cambridge. It is not really false that he studied in Cambridge. Without more, however, the patient is likely to conclude that the doctor did something more than simply spend a weekend in a seminar at a hotel somewhere near Harvard University.

You must also have a reasonable basis for specific advertising claims you make. Claims must be grounded in fact. Specific claims about medical facts or services need to be supported by competent and reliable scientific evidence.[15] What exactly constitutes 'competent and reliable scientific evidence' will depend upon the particular claim. Often, it is defined as 'evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.'[16] Success rate claims would, for example, typically need to be supported by this type of substantiation. Where claims would necessarily require clinical testing to be substantiated, such as claims about drug efficacy, competent and reliable scientific evidence may be held to consist of 'adequate and well-controlled, double-blind clinical testing conforming to acceptable designs and protocols and conducted by persons qualified by training and experience to conduct such testing.'[17] Other types of claims may call for different types of scientific substantiation.

An alternative to advertising that some of you might find more appealing is public education—informing consumers about medical conditions and treatment options to help them make good decisions. This option seems particularly appropriate in the area of impotence treatments. At the FTC, we have observed that deceptive advertising tends to flourish under certain conditions. At least some of them seem present here.

One of these conditions exists when the advertising deals with a subject matter in which the consumer feels some degree of subjective fault or shame. Obesity is one such area; impotence is clearly another. In these cases, the consumers are especially vulnerable. They are frustrated and embarrassed by their condition and want to hear that it is not their fault. They are especially susceptible to claims that their problem can be remedied by a simple treatment requiring little effort on their part.

Another condition that tends to breed misleading advertising arises where the product or service being sold, be it a medical treatment, a technology, or an investment, is in a field that is changing, or at least appears to be changing. Confusion and uncertainty tend to prevail at such times. Consumers are not sure what to believe, and it can be open season on those who want to believe something that is probably just too good to be true. This is also true about impotence treatments. Until recently, conventional wisdom held that impotence was chiefly psychogenic. Today, new drugs and treatment methods are emerging. At the time FTC staff were investigating the Genetus clinics, the US Food & Drug Administration had not yet approved alprostadil. Some of the publicity that occurred at the time

of the FDA's approval probably helped to increase consumer awareness about the treatment options. Still, impotence is not a subject that many consumers feel comfortable discussing, even with their own physicians. Undoubtedly, more can be done to raise the degree of awareness on the part of prospective patients.

A third condition that tends to foster deceptive health care advertising occurs when the research about a particular treatment's effectiveness is not conclusive, or where there is a lack of a consensus among the expert community about treatment protocols. This appears to be less of a problem in the field of impotence treatments than has occurred in other areas, such as the treatment of varicose veins, for example. I found the NIH consensus paper regarding the treatment of impotence dating back to 1992[18] quite useful, and I think that you, as the leading experts, have done a commendable job in developing and presenting a consensus. This is not to suggest that I think you all should agree on each and every step that every physician must take when treating a patient who has experienced impotence. I doubt you would be able to reach such an agreement, in any event. Nevertheless, I do mention the significance of some overall consensus about treatment to make you, as the standard-bearers, appreciate how a well-developed consensus on treatment protocols has a subtle but long-term effect on consumer expectations.

Conclusion

I would like to suggest that public education seems particularly warranted in the case of impotence because it is a harbinger of serious disease. The patient is probably aware of his impotence but may not be aware of the underlying disease. He may not be getting treatment for it. Some of the Genetus ads did serve the important function of correctly warning consumers that impotence is a symptom of serious illness. One of the cruellest hoaxes played by Genetus was that the clinics then proceeded to do virtually nothing to treat the underlying disease. It does seem a shame that the work of educating the public be left to advertising campaigns run by clinics like Genetus.

References

1 *See Virginia Pharmacy Board v. Virginia Consumer Council*, 425 U.S. 748 (1976); *Bates v. State Bar of Arizona*, 433 U.S. 350 (1977).

2 *Bates v. State Bar of Arizona*, 433 U.S. at 364.

3 *Id.* at 368, 377.

4 *Id.* at 372.

5 *Id.* at 383; *Virginia Pharmacy Board v. Virginia Consumer Council*, 425 U.S. at 771-72 and n.24.

6 15 U.S.C. §45(a).

7 *See, e.g., American Medical Association*, 94 F.T.C. 701 (1979), *aff'd as modified*, 638 F.2d 443 (2nd Cir. 1980), *aff'd by an equally divided Court*, 455 U.S. 676 (1982) (order modified 99 F.T.C. 440 (1982), 100 F.T.C. 572 (1982) and 114 F.T.C 575 (1991)); *American Dental Association*, 94 F.T.C. 403 (1979) (consent order) (modified 100 F.T.C. 448 (1982) and 101 F.T.C. 34 (1983)); *American Psychological Association*, 115 F.T.C. 993 (1992) (consent order).

8 *FTC v. Cecil B. Jacobson and Reproductive Genetic Center, Ltd.*, Civ. No. 89-0078-H (E.D. Va.), Consent Judgment entered May 18, 1989. Dr. Jacobson was subsequently indicted by a federal grand jury in Alexandria, Virginia on 53 counts of fraud and perjury. At trial, the Government proved that Dr. Jacobson had deliberately defrauded patients by deceiving them into believing they had become pregnant after undergoing his fertility 'treatments' but that their babies had suddenly died and were 'resorbed' back into their bodies. On May 8, 1992, he was sentenced to five years in prison.

9 *Genetus Alexandria, Inc., et al.*, Docket No. C-3639 (February 12, 1996), —— F.T.C. —— (1996).

10 For example, one Genetus radio advertisement, which featured George Oprean himself, stated:

> *Impotence*. The word itself would strike down the strongest of men, but no more. Medical science has discovered a simple, safe and effective way to treat impotence. I am George Oprean speaking for Genetus where all we do is treat impotence. If you are one of the seven hundred thousand men in this area that are afflicted by impotence, I want you to know that you don't have to suffer anymore. By calling 703/461-9269 you can permanently arrest your impotence. At Genetus, you will be medically evaluated and treated, and when you leave you will be functional—or as I like to say, you're back in business. Impotence is not curable. It knows no age, color or creed. But it is 100% treatable. You no longer have to say I'm sorry or feel guilty. Call 703/461-9269 and find out for yourself what a new beginning feels like. That's 703/461-9269. And believe me, it works.
>
> *See* Exhibit B to the Commission's Complaint.

11 *See* Exhibit C to the Commission's Complaint.

12 As alleged in the Commission's complaint, the Virginia Board of Nursing later revoked Linda Oprean's nursing license.

13 *See Jackson v. Genetus Alexandria, Inc., et al.*, Law No. CL940162 (Circuit Court, Alexandria, Virginia) (Genetus patient brought suit for negligence alleging, among other things, that Genetus failed to conduct an appropriate physical examination, to review and take into account lab results and diagnostic tests prior to administering injections, and to monitor and treat the patient's priapism).

14 *See United States v. George Oprean*, Criminal No. 97-141A (E.D. Va.), Criminal Information, Plea Agreement, and accompanying Statement of Facts entered April 7, 1997.

15 This standard is commonly used in cases involving health claims requiring laboratory testing, expert opinion, or other forms of scientific support. *See Thompson Medical Co.*, 104 F.T.C. 648 821-26 (1984), *aff'd* 791 F.2d 189 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987).

16 *See, e.g., Vein Clinics of America, Inc., et al.*, Docket No. C-3501 (June 24, 1994), 117 F.T.C. 1049 (1994).

17 *See, e.g., Removatron International Corp.*, 111 F.T.C. 206, 312-316, *aff'd*, 884 F.2d 1489 (1st Cir. 1989).

18 NIH Consensus Statement: *Impotence* 1992; **10**(4): 7–9.