HEADNOTE

T-Up, Inc. et al. v. Consumer Protection Division, Office of the Attorney General, No. 0064, September Term, 2001

Consumer Protection Act - Advertising of products for the treatment or cure of, *inter alia*, cancer, AIDS and HIV. Held: Act requires reasonable basis for product claims. Claims for medical products that are to be taken internally for the treatment of life threatening diseases require scientific support by two well-controlled, double-blinded, clinical studies.

REPORTED

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OF MARYLAND

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OFFICE OF THE ATTORNEY GENERAL

Salmon
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This is an action for judicial review of an order by the Consumer Protection Division of the Office of the Attorney General (the Agency). The appellants are Neal Deoul (Deoul), Allen Hoffman (Hoffman), and T-Up, Inc., a Maryland corporation (the Company). The Agency found that the appellants had violated the Consumer Protection Act (the Act), Maryland Code (1975, 2000 Repl. Vol.), Title 13 of the Commercial Law Article (CL), by falsely advertising two products sold by the Company as cures or treatments for, *inter alia*, cancer, AIDS, and HIV. Only the appellant Deoul has briefed and argued the appeal in this Court. He challenges the standard applied by the Agency to determine the falsity of advertising the products involved, the exclusion of certain evidence, and, insofar as it applies to him, the imposition, jointly and severally, of a civil penalty in the amount of $3,706,000.

The Agency found that the appellants had violated the prohibition of CL § 13-303 against engaging in unfair or deceptive trade practices, in this case those defined in CL § 13-301(1), (2), (3), and (9). In relevant part those paragraphs of § 13-301 provide as follows:

> "Unfair or deceptive trade practices include any:
> "(1) False ... or misleading oral or written statement, visual description, or other representation of any kind which has the capacity, tendency, or effect of deceiving or misleading consumers;
> "(2) Representation that:
> "(i) Consumer goods ... or consumer services have a sponsorship, approval, accessory, characteristic, ingredient, use, benefit, or quantity which they do not have;
> ....

> "(3) Failure to state a material fact if the failure deceives or tends to deceive;
>
> ....
>
> "(9) Deception, fraud, false pretense, false premise, misrepresentation, or knowing concealment, suppression, or omission of any material fact with the intent that a consumer rely on the same in connection with:
>
> "(i) The promotion or sale of any consumer goods ... or consumer service[.]"

I

An initial review of the general legal background of this case will assist in understanding the issues presented.

CL § 13-105 declares it to be "the intent of the General Assembly that in construing the term 'unfair or deceptive trade practices', due consideration and weight be given to the interpretations of § 5(a)(1) of the Federal Trade Commission Act by the Federal Trade Commission [FTC] and the federal courts." *See also Luskin's v. Consumer Protection Div.*, 353 Md. 335, 352-54, 726 A.2d 702, 710-11 (1999).

Section 5 of the FTC Act, 15 U.S.C. § 45(a)(1), prohibits "unfair or deceptive acts or practices." Nearly forty years ago the FTC first indicated in *dicta* that a seller of a product violated § 5 of the FTC Act if advertised claims for a product lacked adequate substantiation. *In re Heinz W. Kirchner*, 63 F.T.C. 1282 (1963), *aff'd*, 337 F.2d 751 (9th Cir. 1964). There the FTC stated:

> "[W]e are inclined to think that an advertiser is under a duty, *before* he makes any representation which, if false, could cause injury to the health or personal

> safety of the user of the advertised product, to make reasonable inquiry into the truth or falsity of the representation."

Id. at 1294.

The FTC, in 1972, held that "it is an unfair practice in violation of the [FTC] Act to make an affirmative product claim without a reasonable basis for making that claim." *In re Pfizer, Inc.*, 81 F.T.C. 23, 62 (1972). The Commission, in *Pfizer*, indicated how the interpretation would be applied, saying:

> "The question of what constitutes a reasonable basis is essentially a factual issue which will be affected by the interplay of overlapping considerations such as (1) the type and specificity of the claim made - *e.g.*, safety, efficacy, dietary, health, medical; (2) the type of product--*e.g.*, food, drug, potentially hazardous consumer product, other consumer product; (3) the possible consequences of a false claim - *e.g.*, personal injury, property damage; (4) the degree of reliance by consumers on the claims; (5) the type, and accessibility, of evidence adequate to form a reasonable basis for making the particular claims. *More specifically, there may be some types of claims for some types of products for which the only reasonable basis, in fairness and in the expectations of consumers, would be a valid scientific or medical basis.* The precise formulation of the 'reasonable basis' standard, however, is an issue to be determined at this time on a case-by-case basis. This standard is determined by the circumstances at the time the claim was made, and further depends on both those facts known to the advertiser, and those which a reasonably prudent advertiser should have discovered."

Id. at 64 (emphasis added).

Pfizer's product was a treatment for sunburn, sold as "Un-Burn." Pfizer's ads, *inter alia*, stated that the product "[a]ctually anesthetizes nerves in sensitive sunburned skin." *Pfizer*, 81 F.T.C. at 57. The theory of the complaint in *Pfizer* was

that the ads represented that "each of the statements respecting the pain-relieving properties of Un-Burn has been substantiated by respondent by adequate and well-controlled scientific studies or tests prior to the making of such statements." *Id.* at 58 (italics omitted). The complaint, however, was dismissed because the Commission concluded that the alleged representation reasonably could not be implied from Pfizer's advertising. *Id.* at 59.

Following *Pfizer*, the Commission embarked on a program under which advertisers were required, on demand of the Commission, to submit substantiation for their claims. *See* 3 G.E. Rosden, *The Law of Advertising* § 35.05[4][a] and [b] (2001). In March 1983 the Commission requested comments on its advertising substantiation program. 48 Fed. Reg. 10471 (Mar. 11, 1983). Thereafter, in August 1984, the Commission issued its "Policy Statement Regarding Advertising Substantiation." 49 Fed. Reg. 30999 (Aug. 2, 1984). That statement reaffirmed the FTC's "commitment to the underlying legal requirement of advertising substantiation--that advertisers ... have a reasonable basis for advertising claims before they are disseminated." The Commission announced its intent to "continue vigorous enforcement" of that legal requirement. Where an ad contained a statement "regarding the amount of support the advertiser has for the product claim," the Commission expected the advertiser "to have at least the advertised level of substantiation." If an ad did not express or imply substantiation

for product claims, the Commission nevertheless would assume "that consumers expect a 'reasonable basis' for claims."

Under the 1984 policy statement, which continues in effect, the factors on which the Commission would determine whether a claim was substantiated include

> "the type of claim, the product, the consequences of a false claim, the benefits of a truthful claim, the cost of developing substantiation for the claim, *and the amount of substantiation experts in the field believe is reasonable*. Extrinsic evidence, such as expert testimony or consumer surveys, is useful to determine what level of substantiation consumers expect to support a particular product claim and the adequacy of evidence an advertiser possesses."

(Emphasis added).

The theory of the violations of the Act charged against the appellants in this case is that they lacked reasonable substantiation for their product claims.

II

We turn now to the general facts. In the balance of this opinion, when referring to the Consumer Protection Division in its capacity as the proponent of the charges against the appellants, we shall use "Division." When referring to the Consumer Protection Division in its adjudicatory capacity, we shall use "Agency."

Hoffman holds an Associate of Arts degree from the Community College of Baltimore, granted in 1971. He has worked as a laboratory technician in the Fertility Control Center at Johns Hopkins Hospital, as a salesperson for several medical supply

corporations, as a freelance laboratory technologist, and, in 1994, as an ultrasound technician at a health center in Pennsylvania. Deoul holds degrees of Bachelor of Science and of Juris Doctor, awarded respectively in 1952 and 1959. When the Division sought to take the depositions of Hoffman and Deoul each deponent invoked his Fifth Amendment privilege against self-incrimination. As a sanction for their refusal to testify the Administrative Law Judge (ALJ) before whom the evidentiary hearing on the charges was held precluded Hoffman and Deoul from testifying.

The Agency found that Hoffman and Deoul each falsely represented himself to hold a Ph.D. degree. Hoffman's misrepresentation included a fraudulent Ph.D. diploma, purportedly awarded by the University of Heidelberg in Germany.

The Company was formed in early November 1996. Hoffman and Deoul each held 42.3% of the issued and outstanding shares. Hoffman was president and treasurer while Deoul was vice-president and secretary. Deoul loaned the Company $120,000 at its inception. The organizational minutes of the Company recite that it accepted "technology" from both Deoul and Hoffman.

The Company marketed and sold "T-Up," a concentrated aloe vera extract, and cesium chloride, a mineral, as alternative medical treatments for numerous diseases and conditions.[1] Working from

[1]Aloe vera (Aloe barbadensis Miller) is a member of the lily family.

purchased mailing lists, the Company mailed to consumers an audio tape, featuring Hoffman and entitled "There is Hope." The tape is in the format of a lecture before a live audience, followed by a question and answer period. A narrator opens and closes the recording. At the end of the recording listeners are told, "You and you alone can avoid becoming another statistic. Act now and call this number to order: 410-486-5200. That's 410-486-5200."

That number rang in the office of the Company in the Baltimore metropolitan area. There a staff of telephone answering sales representatives worked from a desk reference manual and from price lists. The thirty page desk reference manual described how the products worked, what the recommended dosages were for various diseases, and, in some instances, the purported success rate of the products in treating various diseases. When the Company filled an order from a consumer, the shipment to the customer was accompanied by a brochure entitled, "Boost Your Immune System."

Both the brochure and the audiotape claim that T-Up is capable of boosting the body's immune system and thus of helping individuals who are afflicted with a wide range of immune-related illnesses. The letter covering transmittal of the tape and signed by Hoffman states that the Company has learned to "manipulate" the immune system so "that the body can heal itself." The advertising matter focuses on T-Up's claimed ability to fight cancer, AIDS, and

HIV, but similar claims also are made with regard to lupus, herpes, and arthritis, among other conditions.[2]

The advertisements for T-Up and cesium chloride are replete with broad statements about the disease-fighting powers of these products. The following is but a sample of such statements about T-Up:

> --"T-UP is effective in the treatment of most malignancies except pancreatic and brain cancers. Prostate cancer, which is slow growing tissue, responds particularly well to treatment with T-UP."
>
> --"In the treatment of liver cancer, T-UP has been extremely successful because the liver is highly vascular and there is no problem getting into it."
>
> --"[W]e could double the number of T-4 lymphocytes ... [which] are the cells that people with HIV lose ... roughly every three weeks ....
>
> "... Then we noticed further that after a short period of time not only were we increasing the number of the cells that these folks were losing but we noticed a decrease in viral lode, that is a decrease in the virus that was affecting them."

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[2]One of the appellants' experts, Lawrence Pearce, M.D., explained in lay terms his opinion on how T-Up interacted with the immune system. He said that autoimmune disorders result from an overactive immune system, in which there is an overproduction of antibodies, and healthy tissue is attacked. Aloe vera, in his view, stimulates the production of T8 lymphocytes, which helps to restore the immune system's balance.

With other immune system disorders, he said that the problem is not overstimulation but rather a malfunctioning of "killer" cells, which enable the body to fight toxins, microbes, and tumor cells. The role of aloe vera in fighting these diseases is to enhance the immune system's attack.

> --"In rheumatoid arthritis, we're dealing with an autoimmune response and we're going to be extremely effective."
>
> --"The herpes virus, much like many of the other viruses, can be controlled with the administration of Aloe vera."
>
> --"[W]e do real well if you know anybody with chronic fatigue."

The Company also promoted a combination package of T-Up and cesium chloride for treating cancer. On the audio tape Hoffman in part says:

> "[C]esium chloride begins to destroy malignant tissue in three days. And my experience recently is that in ten days 50% of a malignancy will disappear. The rest of the malignancy based upon scientific literature should disappear within two to three months."

Based on a statement in the desk reference manual, the Company's sales representatives told consumers that the Company had had a "100% success rate" in treating breast cancer with cesium chloride. That representation was discontinued, on the advice of counsel, during the fall of 1997.

Between October 1996 and May 1998 the Company mailed the audio tape to 125,000 names on mailing lists. It was stipulated that in the six month period from April 1997 through October 1997 the Company had a total of 3,706 customers. The former office manager of the Company estimated that the majority of the Company's customers suffered from cancer and that one-third of those were in late stages.

The Company's supplier of T-Up was Cosmetic Specialty Labs, Inc. of Lawton, Oklahoma, the president of which, Odus M. Hennessee, was a five percent shareholder in the Company. Between September 25, 1996, and October 1, 1997, Cosmetic Specialty Labs shipped 32,620 two ounce bottles of T-Up to the Company. T-Up was also sold in liquid form in other sizes and as a salve, a suppository, and a douche. A sterile form of T-Up was sold for intravenous injection, which ostensibly was to take place under the care of a physician outside of the United States.

The two ounce liquid concentrate form of T-Up retailed at $75 per bottle for purchases of less than twenty bottles. The cost to the Company of a two ounce bottle of T-Up ranged from $15.37 to $20.37. A container of 100 capsules of 500 mg. cesium chloride retailed at $75 per container when less than twenty containers were purchased. The cost to the Company of a 100 capsules container was $20.50.

Additional facts will be stated in the discussion of particular issues.

III

In the fall of 1997 both the Food and Drug Administration (FDA) and the Division launched investigations of the Company's activities. The statement of charges that is before us was filed in May 1998, and the matter was referred to an ALJ for hearing.

The hearing encompassed twenty-seven days between October 1998 and April 1999.

It appears that, during the pre-hearing phase of this matter, the Division called upon the appellants to produce all documents which the appellants asserted substantiated their claims for T-Up and cesium chloride. At the hearing the Division introduced Exhibit 56, consisting of seventy-nine subparts and containing eighty-five articles from publications, including scientific journals. The extent of any scientific literature support for the appellants' claims lies within Exhibit 56. Consequently, expert witnesses for both sides directed a considerable portion of their testimony to the significance, *vel non*, of Exhibit 56.

One of the experts called by the Division, Dr. Richard Humphrey, is an Associate Professor of Pathology, Medicine, and Oncology, at the Johns Hopkins School of Medicine. For nearly two decades he was the Director of the oncology teaching program at that medical school. For approximately sixteen years he also was the Director of the Diagnostic Immunology Laboratory at the Johns Hopkins Hospital.

The Division also called Dr. Joel Gallant, an Associate Professor of Medicine at Hopkins and the Director of its clinic for patients afflicted with any stage of HIV disease, including AIDS.

Doctors Humphrey and Gallant explained the multi-step process of testing that is required before the medical efficacy of an

experimental substance for treatment of an illness in human beings is generally accepted in the medical-scientific community. First, the experimental substance must be consistent from one lot to another in production. Next, it is tested "in vitro," *i.e.*, in a laboratory setting using tissue culture cells, followed by "in vivo" testing on animals. If, at those steps, the experimental substance is shown to be both safe and efficacious, it is tested on humans through three sequential phases. Phase one usually involves a small number of healthy people who receive varying dosages to determine if the substance is toxic in humans. Phase Two also involves a relatively small number of patients who are divided into two groups, one of which receives the experimental substance and the other of which receives either the then standard treatment substance or a placebo. The patients do not know which treatment they are receiving. Phase three of human testing usually consists of a number of simultaneous projects at different medical institutions involving relatively large numbers of patients engaged in "double-blinded" studies. In such studies neither the patient nor the scientist who initially evaluates a patient's response to the treatment knows which treatment the particular patient has received.

Doctors Humphrey and Gallant respectively reviewed Exhibit 56 in preparation for their testimony. They each concluded that nothing in Exhibit 56 substantiated the Company's claims for its

products by the type of scientific evidence described in their testimony. They explained why certain published articles that were produced in Exhibit 56 and that had some relevancy did not demonstrate the efficacy of T-Up and cesium chloride in the treatment of humans for disease, including cancer, AIDS, or HIV. The ALJ and the Agency accepted this testimony. This gives rise to the first issue which we address on this appeal, *i.e.*, whether the Agency, as a matter of law, applied an erroneous standard.

In the defense case at the hearing, the appellants called as experts, Robert Barefoot, John Heggers, Ph.D., and Lawrence Pearce, M.D. Doctors Heggers and Pearce testified extensively, but, in certain areas the ALJ sustained objections by the Division and limited their testimony. In addition, the appellants called a number of customer witnesses who testified concerning their satisfaction with the Company's products, but the appellants were not allowed to introduce, in addition, eighty affidavits from customers to the same general effect. Nor did the ALJ accept an affidavit from a registered pharmacist concerning the legality of intravenous injection of "sterile" T-Up.

Based on its findings of violations of the Act, the Agency entered an extensive order, containing numerous injunctive provisions, including a requirement that the Company's advertising affirmatively state that intravenous use of T-Up is illegal in the United States. The Agency also imposed the maximum fine of $1,000

per violation under CL § 13-410(a), treating the stipulated total of 3,706 customers during the April 1997 through October 1997 period as representing one violation per customer. In this Court Deoul vigorously contends that there was insufficient evidence to support his inclusion, jointly and severally with the other appellants, in liability for that fine.

Appellants sought judicial review of the Agency decision before the Circuit Court for Baltimore County, which, with one modification not relevant here, affirmed the Agency decision. This appeal, and a brief by Deoul, followed.

IV

Deoul raises the following questions, which we have reordered and rephrased:

> 1. Whether the Agency erred as a matter of law by imposing a rigid prerequisite of two well-controlled, double-blinded clinical studies proving safety and efficacy before any health claims about aloe vera or cesium chloride could be made?
>
> 2. Whether the ALJ's refusal to qualify Deoul's expert witnesses, and restrictions on the scope of their examinations, constituted an abuse of discretion and reversible legal error?
>
> 3. Whether the ALJ abused her discretion by excluding from evidence the affidavit of Karen Weaver?
>
> 4. Whether the Agency lacked substantial evidence to support its order forcing appellants to represent in connection with any future sale of aloe vera that its intravenous use is illegal?
>
> 5. Whether the ALJ's refusal to admit into evidence eighty (80) consumer affidavits constituted an abuse of discretion?

6. Whether, by limiting the number of consumer witnesses who could testify, the ALJ abused her discretion in view of her prior representation that she would accept affidavits from these excluded witnesses?

7. Whether the Agency lacked substantial evidence to support its ruling that Deoul was personally liable for the wrongs of the Company?

V

In reviewing the decision of an administrative agency, "we reevaluate the decision of the agency, not the decision of the lower court." *Gigeous v. Eastern Correctional Instit.*, 363 Md. 481, 495-96, 769 A.2d 912, 921 (2001) (citing *Public Serv. Comm'n v. Baltimore Gas & Elec. Co.*, 273 Md. 357, 362, 329 A.2d 691, 694-95 (1974)). Under the Administrative Procedure Act, this Court's review is governed by the standard and scope of review imposed upon the circuit court. *See* Maryland Code (1984, 1999 Repl. Vol), § 10-222(h) of the State Government Article.

The scope of our review of administrative agency action is narrow and we are "not to substitute [our] judgment for the expertise of those persons who constitute the administrative agency." *United Parcel Serv., Inc. v. People's Counsel for Baltimore County*, 336 Md. 569, 576-77, 650 A.2d 226, 230 (1994) (internal quotations omitted). Accordingly, this Court is tasked with "'determining if there is substantial evidence in the record as a whole to support the agency's findings and conclusions, and to determine if the administrative decision is premised upon an erroneous conclusion of law.'" *Board of Phys. Quality Assurance v.*

Banks, 354 Md. 59, 67-68, 729 A.2d 376, 380 (1999) (quoting *United Parcel Serv.*, 336 Md. at 577, 650 A.2d at 230).

With regard to questions of fact, we will only disturb the decision of an administrative agency if "a reasoning mind reasonably could [not] have reached the factual conclusion the agency reached." *Baltimore Lutheran High Sch. Ass'n v. Employment Sec. Admin.*, 302 Md. 649, 662, 490 A.2d 701, 708 (1985). Thus, "[a] reviewing court should defer to the agency's fact-finding and drawing of inferences if they are supported by the record." *Banks*, 354 Md. at 68, 729 A.2d at 380-81. With regard to questions of law, "an administrative agency's interpretations and application of the statute which the agency administers should ordinarily be given considerable weight by reviewing courts." *Id.* at 69, 729 A.2d at 381. Such deference, however, is not warranted when the agency's construction "override[s] the plain meaning of the statute or extend[s] its provisions beyond the clear import of the language employed." *State Dep't of Assessments & Taxn. v. Greyhound Computer Corp.*, 271 Md. 575, 589, 320 A.2d 40, 47 (1974).

VI
(Issue 1)

The standard which the Agency required the appellants to meet in order to substantiate their product claims is set forth most clearly in the Agency's final order. It directs the appellants to cease and desist from making any representations concerning the "efficacy, performance, safety or benefits" of the Company's

products "unless, at the time the representation is made, [appellants] possess and rely upon competent and reliable scientific evidence that substantiates the representation." The order further defines "competent and reliable scientific evidence" to mean:

> "tests, analysis, research, studies, or other 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. For health products such as those sold by [appellants], competent and reliable scientific evidence shall include *at least two* adequate, and well-controlled, double-blinded clinical studies."

(Emphasis added).

The Agency concluded, based largely on the testimony of Drs. Humphrey and Gallant, that there were *no* scientifically reliable tests in evidence that established aloe vera or cesium chloride as an effective treatment or cure for any form of cancer or for HIV or AIDS.[3] Deoul's position is that the Agency erred by requiring two

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[3]Two examples from this voluminous record may give the reader a glimpse of where the scientific community currently stands with respect to the issues in this case. An article, "Aloe Vera and Cancer," that appeared in an English publication by Biomedical Information Services Ltd. in 1996 in part reads:

> "There appear to have been no trials organised to discover whether or not *Aloe vera* is effective or supportive in cancer treatment. Therefore, the evidence we have is of a lesser kind. At this stage it would, indeed, be grossly irresponsible of anyone to offer *Aloe vera* as an effective cancer treatment or, even worse, as *the cure* for cancer. Nonetheless, the indications that are available from the literature, showing that *Aloe vera*

(continued...)

clinical studies because, under the *Pfizer* test, a reasonable basis can be found to substantiate the Company's product claims from other forms of evidence and without any well-controlled, double-blinded, clinical, human studies in evidence supporting the Company's representations.

The cases applying § 5 of the FTC Act require clinical study support for products that are to be ingested by humans or applied to the human body, and many of these cases require two such studies. In *FTC v. Pantron I Corp.*, 33 F.3d 1088 (9th Cir. 1994), *cert. denied*, 514 U.S. 1083, 115 S. Ct. 1794, 131 L. Ed. 2d 722 (1995), the claim was that the advertiser's product, "The Helsinki Formula," promoted the growth of new hair on men with male pattern baldness. Studies on which Pantron relied, conducted in Finland and in France, were uncontrolled and unblinded. *Id.* at 1093. The

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[3](...continued)
has an anti-cancer effect, either upon cells in tissue culture, or in the living animal, are most impressive. Of course, effectiveness in animals cannot be safely extrapolated to effectiveness in human cases. It is amazing, however, that in view of all the positive indications which exist for the anti-cancer effects of *Aloe vera*, that no medical studies have been initiated in human cancer."

An article dealing with a well-controlled test on humans of acemannan, a principal ingredient of aloe vera, is reported in 12 Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology (1996) by J.S.G. Montaner, et al., entitled "Double-Blind Placebo-Controlled Pilot Trial of Acemannan in Advanced Human Immunodeficiency Virus Disease." The researchers found no statistically significant difference between the acemannan-treated and placebo-treated groups with respect to various scientific markers of the progress or decline of progressive HIV disease.

FTC, however, introduced two studies, one of which was placebo-controlled, double-blinded, and randomized. *Id.* at 1092-93. The Ninth Circuit reversed that portion of the district court's injunction which permitted Pantron to advertise that its product was effective with some persons because "[s]cientific studies recognized under standards in use in the United States" failed to explain or support, and in fact refuted, the effectiveness claims. *Id.* at 1101. *See also Removatron Int'l Corp. v. FTC*, 884 F.2d 1489 (1st Cir. 1989) (at least one well-controlled, double-blinded clinical test necessary to support permanent hair removing result claimed for advertiser's radio frequency energy emitting tweezers); *Thompson Med. Co. v. FTC*, 791 F.2d 189 (D.C. Cir. 1986) (denying review of FTC order requiring advertiser to have at least two adequate and well-controlled, double-blinded clinical studies to support claims of topical analgesic's effectiveness in treating arthritis), *cert. denied*, 479 U.S. 1086, 107 S. Ct. 1289, 94 L. Ed. 2d 146 (1987); *Sterling Drug, Inc. v. FTC*, 741 F.2d 1146 (9th Cir. 1984) (affirming FTC order requiring two well-controlled clinical studies to support advertiser's claim of superiority for its internal analgesic over competing products), *cert. denied*, 470 U.S. 1084, 105 S. Ct. 1843, 85 L. Ed. 2d 142 (1985); *American Home Prods. Corp. v. FTC*, 695 F.2d 681 (3d Cir. 1982) (requiring two well-controlled clinical studies to support advertiser's claim of superior effectiveness and freedom from side effects for its non-

prescription analgesics); *Porter & Dietsch, Inc. v. FTC*, 605 F.2d 294, 302 n.5 (7th Cir. 1979) (applying the *Pfizer* factors to diet tablets and concluding that the only reasonable basis to support claims "'would be a valid scientific or medical basis'"), *cert. denied*, 445 U.S. 950, 100 S. Ct. 1597, 63 L. Ed. 2d 784 (1980); *In re Viral Response Sys., Inc.*, [1987-1993 Transfer Binder] Trade Reg. Rep. (CCH) ¶ 23,135 (FTC Jan. 27, 1992) (consent order prohibiting advertising of device for blowing air and medicated sprays into nasal passages as, *inter alia*, destroying antibodies involved in allergic reactions, unless two well-controlled, double-blinded clinical studies support the claim).

The numerical and persuasive weight of authority dealing with products that are intended to be taken internally requires two clinical studies. The obvious purpose of a second study is to see if the results claimed in one study are reproducible and confirmed by another study. Here, we are dealing with the advertising of purported cures or treatments for life-threatening diseases. Applying the FTC cases, we hold that the Agency did not err in concluding that a reasonable basis for such product claims requires at least two adequate, well-controlled, double-blinded clinical studies. Hereinafter we call this level of support the "Standard."

VII
(Issue 2)

We turn to Deoul's assertions that the testimony of certain of the experts called by the defense was limited erroneously. A decision to admit or exclude expert testimony is within the discretion of the administrative tribunal and will be upheld so long as the basic rules of fairness are observed. *See Dickinson-Tidewater, Inc. v. Supervisor of Assessments*, 273 Md. 245, 253-54, 329 A.2d 18, 24 (1974).

A

Robert Barefoot (Barefoot), a chemist, was called by Deoul as an expert on cesium chloride. According to a written proffer filed by Deoul, the ultimate opinion to be expressed by Barefoot was that the Company's representations in the audio tape and in the brochure with respect to the efficacy and safety of cesium chloride in the treatment of many forms of cancer are accurate. More specifically, Deoul sought to qualify Barefoot in "the use of cesium chloride in conjunction with high pH therapy and its effect on the chemistry of the human body," in order to explain why the representations were accurate.

In 1982 Barefoot became interested in diseases caused by mineral and vitamin deficiencies. He has read extensively on the subject and has written or coauthored two books in which his central premise is that "most ... degenerative diseases are caused by mineral and vitamin deficiency." Since about 1992 Barefoot has

given hundreds of lectures on this subject and currently devotes approximately seventy-five percent of his time to this pursuit.

After hearing testimony on voir dire and argument that cover approximately 100 pages of transcript, the ALJ refused to qualify Barefoot as an expert on the use of cesium chloride on humans in conjunction with high pH therapy for the following reasons.

> "This area of expertise pertains primarily to knowledge of the human body and its chemistry, and it requires ... an expert in the human body and its chemistry.
>
> "This witness has formal education and professional training in inorganic chemistry and he has an interest in matters of organic chemistry and biochemistry in the human body. However, he has not had any professionally supported or professionally supervised training in these areas, nor has he done any professionally competent research in these areas.
>
> "... He testified that he did not collaborate in professionally designed research with any other professional and instead relied on information from other people, both through reading and through discussions."

The ALJ also reasoned that Barefoot's opinion, based upon discussions with doctors and conversations with cancer patients, would not be admitted because it was not part of a systematic or formal study.

Deoul argues that an expert's opinion may be based on the proffered expert's experience, including study and discussions with others. Although we have no quarrel with the general concept that an expert may be qualified "by knowledge, skill, experience, training, or education," Maryland Rule 5-702, here Deoul sought to

substantiate through Barefoot the medical efficacy and safety claims of appellants.

In his proffer Deoul refers to eight papers in Exhibit 56 as support for Barefoot's opinion, but only one contains a clinical study involving humans. That is a paper by H.E. Sartori, "Cesium Therapy in Cancer Patients," 21 Pharmacology, Biochemistry & Behavior, Supp. 1, at 11 (1984). While that paper reports on fifty cancer patients who were studied, on its face it is not a controlled, double-blinded study. Thus, the proffered opinion is not relevant on the issue of a violation of the Act because it does not meet the Standard.

The same result is reached under an analysis of the law concerning expert opinions on new scientific developments. The Court of Appeals has stated, in the Court approved committee note to Rule 5-702, that the rule is not intended to overrule the *Frye-Reed* doctrine. See *Reed v. State*, 283 Md. 374, 391 A.2d 364 (1978); *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923). Barefoot testified on voir dire that,

> "if you search the scientific literature, there are absolutely no doctors that ... published anything on cesium. So, therefore, they must go to the chemical world. You look at the chemical world, there are thousands of publications, but there's only maybe four concerning the biology. So, in other words, there are no experts except for those like myself."

By Barefoot's own admission, his beliefs as to the efficacy of cesium chloride in the treatment or cure of cancer do not have general scientific acceptance.

Under Federal Rule of Evidence 702 general acceptance in the scientific community is not a necessary precondition to the admissibility of scientific evidence. *See Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993). The Court there recognized that federal trial judges would have a gatekeeping role with respect to the admissibility of opinion scientific evidence and, as guidance, presented factors for deciding admissibility. These were whether the theory can be and has been tested, 509 U.S. at 593, 113 S. Ct. at 2796, whether it has been subject to peer review, *id.*, 113 S. Ct. at 2797, the known or potential rate of error, *id.* at 594, 113 S. Ct. at 2797, and "general acceptance." *Id.* The Court emphasized that "in order to qualify as 'scientific knowledge,' an inference or assertion must be derived by the scientific method," *id.* at 590, 113 S. Ct. at 2795, and that "'[science] represents a *process* for proposing and refining theoretical explanations about the world that are subject to further testing and refinement.'" *Id.* (quoting Amicus Brief for American Association for the Advancement of Science).

In the instant case the ALJ took extensive testimony from Barefoot in which he described his many discussions with doctors and patients in one way or the other involved in the use of cesium

chloride in the treatment of various forms of cancer. The ALJ concluded that "this experience and study was not scientific." His experiences seem not to have been a formal study, had not been subject to well-controlled testing on humans, and had not been subject to peer review of any consequence. Accordingly, under *Frye-Reed* or *Daubert*, there was no abuse of discretion in excluding the proffered opinion of Barefoot.

In his brief in this Court Deoul for the first time argues that Barefoot's proposed opinion would be relevant on the issue of the civil fine and Deoul's good faith.[4] Deoul's proffer, however, does not represent that any admissible evidence concerning his state of mind could be produced through Barefoot, and Deoul, of course, was precluded from personally giving any such evidence because of his refusal to testify on deposition. Further, it was incumbent on Deoul, once the ALJ ruled that Barefoot's opinion evidence would not be admitted, to point out any special relevance that it might have, but Deoul did not do so.

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[4]CL § 13-410(d) provides that the Agency

"shall consider the following in setting the amount of the penalty imposed in an administrative proceeding:
"(1) The severity of the violation for which the penalty is assessed;
"(2) The good faith of the violator;
"(3) Any history of prior violations;
"(4) Whether the amount of the penalty will achieve the desired deterrent purpose; and
"(5) Whether the issuance of a cease and desist order, including restitution, is insufficient for the protection of consumers."

B

Deoul called as a witness a biologist, John Heggers, Ph.D. (Heggers). Deoul announced his intention to qualify Heggers as an expert in microbiology, clinical microbiology, immunology, and bacteriology. The ALJ accepted the witness as an expert in immunology, microbiology, and the laboratory analysis of aloe vera. Deoul complains that the ALJ did not permit Heggers to state his opinion on the effectiveness of aloe vera to treat cancer, HIV, or AIDS. We find no preservation and, if preserved, no error, and, if error, no prejudice.

Dr. Heggers is certified as a medical technologist and a clinical laboratory director. He currently serves as a professor in the departments of surgery and of microbiology and immunology at the Graduate School of the University of Texas Medical Branch and as the Director of Clinical Microbiology at the Children's Burn Hospital in Galveston, Texas. He has specialized in the treatment of burns and wounds and, in particular, the use of aloe vera in such treatment.

Deoul refers to Dr. Heggers's having participated in two published studies pertaining to cancer. One involved reconstructive surgery of the mouth and the other tests on animals. His assistance in those studies dealt with bacterium. He serves as a member of a hospital team that conducts monthly morbidity and mortality evaluations of cancer patients.

Deoul cites *Wolfinger v. Frey*, 223 Md. 184, 162 A.2d 745 (1960), and *Radman v. Harold*, 279 Md. 167, 367 A.2d 472 (1977), for the proposition that "a physician may testify as an expert witness, even if that physician is not a specialist in the area in which he wishes to testify." These cases, however, are inapposite because Dr. Heggers does not hold a medical degree.

Heggers's testimony and arguments over the admissibility of portions of it comprise 330 pages of transcript and two days of the hearings. The ruling by the ALJ to which Deoul takes exception should be placed in perspective. After Heggers had been qualified as an expert in the three fields set forth above, he opined, based upon studies included in Exhibit 56, "that the T-Up product is essentially as proposed in the medical representations [in the audio tape and brochure]. It has the capability and quality to do that." Then, in a lengthy direct examination, Heggers reviewed and explained how nineteen of the Exhibit 56 articles supported his opinion that the product claims were accurate. Heggers gave his views on the relationship between the immune system and cancer, HIV, and AIDS. Heggers expressed his disagreement with the statement in one of the Exhibit 56 articles, see note 2, *supra*, that it would be grossly irresponsible to offer aloe vera as "an effective cancer treatment." When asked if he had "an opinion to a reasonable degree of scientific certainty as to whether T-Up can

effectively treat autoimmune disorders," he stated his belief "that T-Up can be utilized as a product for autoimmune diseases."

The ALJ sustained the Division's objections to Heggers's stating opinions on the effectiveness of T-Up in treatment, on one occasion as to HIV and AIDS, and, on another occasion, as to cancer. The claim of error has not been preserved as to either ruling. There is no proffer on the record at the time of either ruling, and Deoul has not furnished us with a record reference to any claimed proffer.

Heggers acknowledged that none of the studies in Exhibit 56 were double-blinded studies. Thus, under our holding in Part VI, *supra*, as to the Standard, his opinion, based on certain articles in Exhibit 56, that the representations in the Company's advertising matter were accurate, was more beneficial to appellants than they had a right to have in evidence. Disallowing any further expansion on that opinion was not error.

We also agree with the ALJ's ruling that Heggers was not qualified to express an opinion on the treatment of all of the cancers involved in the Company's claims, or on the treatment of AIDS and HIV. Although he is neither an oncologist nor an infectious disease specialist, this is not a case where a witness was disqualified "*merely* because he is not a specialist or ... has never personally performed a particular procedure." *Radman*, 279 Md. at 171, 367 A.2d at 475. Rather, this is a case of a non-

physician witness being disqualified because he lacks "sufficient knowledge 'to express a well-informed opinion,'" *id.* at 173 n.2, 367 A.2d at 475 n.2 (citation omitted), about the efficacy of aloe vera in the treatment of cancer, HIV, or AIDS. The ALJ acted within her discretion when she concluded that further expressions of Dr. Heggers's personal opinion would not give her scientific guidance.

In any event, the rulings, if erroneous, are not prejudicial. Heggers's direct examination concluded with an item-by-item review of every representation in the audio tape and in the brochure, as to each of which Heggers explained why he believed the representation was accurate. In that connection he said that the following statement from the brochure was accurate: "'In fact, T-Up appears to be capable of increasing T-lymphocytes and attacking cancer, AIDS, herpes, and other viruses like nothing else before it.'"

Later, Dr. Heggers was asked to opine on the accuracy of the following statement in the Company's advertising:

> "'Aloe contains at least 23 polypeptides (immune stimulators) which help control a broad spectrum of immune system diseases and disorders. The polypeptides plus the antitumor agents, emodine and lectins explain aloe's ability to control cancer.'"

When the State objected, arguing a lack of qualifications to opine on the treatment of cancer, Deoul replied that Dr. Heggers

> "has testified in great length ... in going through the --many of the State's exhibits in 56 how aloe vera is

> effective in treating many illnesses, including cancer. He's already testified ad nauseam on the subject."

There is no basis on which to conclude that the ALJ prejudicially limited the examination of Dr. Heggers.

C

Larry Pearce, M.D., came from Moxville, North Carolina to testify for the appellants. His testimony and the argument of counsel over the admissibility of portions of it consumed over three days and 450 pages of transcript. Deoul complains that the ALJ did not accept Dr. Pearce as an expert in the diagnosis and treatment of immune and autoimmune disorders, and that she did not accept him as an expert on the effect of aloe vera on the human body.

Dr. Pearce holds a medical degree from Wake Forest University. He has practiced and taught in the area of neurology, but he has no formal training in immunology. His professional work has dealt primarily with understanding the "neuropharmacologic interventions" involved in multiple sclerosis (MS). Currently he treats one-third of his patients for MS, one-third for Parkinson's disease, and one-third for pain management. Dr. Pearce has engaged in clinical work and research of the immune system as it relates to MS, but he has not performed clinical studies or published research on aloe vera or cesium chloride. In his thirty-three years of medical practice he treated many patients *with* cancer, but not specifically *for*

cancer. He acknowledged that cancer is not his "area of expertise .... I'm not an oncologist."

In his voir dire Dr. Pearce was asked to identify the illnesses caused by an improperly functioning immune system with which he had practical clinical experience. Dr. Pearce modified the question by limiting it to "[n]eurologic illnesses that are associated with an autoimmune problem." His answer to the question as limited did not include cancer, HIV, or AIDS, the three principal diseases about which the Company made representations.[5]

Because Dr. Pearce was the only witness whom Deoul called to testify as an expert who held a medical degree, Deoul at oral argument in this Court emphasized that the lack of specialization in the relevant field and of personal experience in performing a specific procedure is not a per se disqualification from testifying as a medical expert. The principal case relied on is *Radman v. Harold*, *supra*, 279 Md. 167, 367 A.2d 472, a medical malpractice case. There, the female plaintiff's expert was an internist who

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[5]In his answer to the question, as modified, Dr. Pearce said:

> "[M]ultiple sclerosis, myasthenic gravis, chronic demyelinating polyneuropathy, Hashimoto's disease, one that affects the nervous system indirectly called dementia, if there is too low a thyroid, lupus parasthenia which is basically a rheumatology disease but has such a neurologic component that it becomes part neurology and part rheumatology.
>
> "So I see patients with lupus, systemic lupus which have brain involvement because of their autoimmune dysfunction."

would have testified that the defendant surgeon failed to meet the standard of care when performing a total abdominal hysterectomy by unintentionally nicking the plaintiff's bladder. The Court of Appeals held that the trial judge had erred in excluding the proffered opinion based on the mistaken belief that specialization or actual experience was a legal prerequisite to qualifying as an expert on the standard of care in performing a total hysterectomy. The Court pointed out that generally, and including the field of medicine, "the degree of knowledge, skill, and experience required of a witness depends entirely on the area under investigation." *Id.* at 171 n.2, 367 A.2d at 475 n.2. In view of its holding, the Court of Appeals did "not reach the question whether there was an abuse of discretion." *Id.* at 176, 367 A.2d at 477. The case was remanded for retrial at which a determination of the expert's qualifications would be "based on his overall familiarity with the procedures in dispute, and the trial court should exercise its discretion in a manner consistent with the legal principles set out in [the *Radman*] opinion." *Id.*

Radman does not give a holder of a medical degree carte blanche to opine on any subject having a medical context. In the case before us the issue was whether the appellants had a reasonable basis for making their representations concerning the efficacy of the Company's products. The ALJ clearly exercised discretion in not accepting Dr. Pearce as an expert in the

diagnosis and treatment of immune and autoimmune disorders, generally, or in the effect of aloe on the human body. After considering the voir dire she noted that he had done no research in those areas, he had had no formal education in the area, and he had not done any systematic study or review of the effects of his treatments on patients with immune or autoimmune diseases. In view of what we have held to be the Standard for substantiating claims of cures or treatments for life-threatening diseases, the ALJ did not abuse her discretion in this ruling.

Moreover, Deoul did not in his brief point to any proffer in the record setting forth the anticipated answers to a line of examination which Deoul contends were admissible but which were excluded because of the challenged ruling. Consequently, appellate review of the asserted error has not been preserved.

By parenthetical references to the record extract Deoul apparently undertakes to illustrate what Dr. Pearce's testimony would have been by pointing to four other rulings during his examination, after he had failed to qualify in the two fields described above. The context of the questions makes plain that they did not seek to elicit opinions based on studies meeting the Standard.

In the first line of questioning Dr. Pearce explained that an autoimmune disorder means that the immune system has gone awry and cannot shut itself off, particularly in the production of

antibodies. He said that he has utilized T-Up in treating patients suffering from MS and that they benefitted by being less fatigued. He is of the opinion that the existing literature presented sufficient reliable scientific research on aloe vera to substantiate his uses of it. He explained that aloe vera is "a modulator of the immune system." Against that background Dr. Pearce was asked: "Does the use of Aloe Vera ... increase the production of T4 cells?" The ALJ sustained an objection, reasoning that Dr. Pearce was not an expert in the medical effects of aloe vera on the human body. Absent a proffered answer, Deoul has not pointed out how the answer would have produced new matter that was not substantially covered elsewhere in Dr. Pearce's extensive testimony.

Deoul complains because Dr. Pearce was not permitted to testify whether a specified article from among the articles in Exhibit 56 supported the appellants' representations in the audio tape and brochure that aloe vera was an effective treatment of some forms of cancer. If preserved, there was no error. Dr. Pearce admitted that he had no training as an oncologist and no experience in the treatment of cancer. Given the lack of general scientific acceptance of aloe vera as a cancer cure, the ALJ properly could conclude that the subject was not one on which Dr. Pearce, based on

his medical degree, could render an opinion that would be of assistance.[6]

Deoul, adopting Hoffman's position, sought to have Dr. Pearce accepted as an expert in the relationship between the human immune system and diseases. The ALJ declined to do so. Once again, there is no proffer and no indication that Dr. Pearce's anticipated answer would extend beyond the testimony that he had already given. It is also clear that he had little, if any, experience in treating immune disorders, other than MS. In any event, immediately after the objection was sustained, Dr. Pearce testified that, based on his independent study, aloe vera has the ability to increase T-lymphocytes.

The fourth ruling complained of arose after Dr. Pearce had testified for approximately 425 pages of transcript. His attention was directed to the text of audio tapes produced by a Dr. Darryl See and dealing with the relationship of glyco nutrients to the immune system. Aloe vera contains glyco nutrients. Dr. Pearce was

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[6]The ALJ, however, allowed Dr. Pearce to testify generally as to the relationship between an improperly functioning immune system and various forms of cancer. He stated:

> "It is now a well accepted concept in medicine, particularly as it relates to oncology in my opinion, that the immune system is extremely strategic in not only preventing cancers from developing, but once they have been established, the immune system is extremely important, an intact immune system is extremely important in the body's defense against the tumor itself and the possibility of the body getting rid of it."

asked to identify the illnesses described in tape three of the See collection that were autoimmune diseases. He identified lupus, but the ALJ in effect struck that testimony. The error, if any, was not prejudicial because Dr. Pearce had testified, much earlier, that lupus is an autoimmune disorder. Further, inasmuch as representations concerning lupus are, within the framework of Deoul's appeal, secondary, at best, to the representations concerning cancer, HIV, and AIDS, the ruling, if erroneous, is not prejudicial on that ground as well.

VIII
(Issue 3)

The Agency found that Deoul, Hoffman, and the Company's staff made numerous referrals of consumers with late stage cancer to a Dr. Donald MacNay of Virginia and, to a lesser degree, other physicians for the purpose of having those physicians inject the patients with sterile T-Up. In an August 1997 radio broadcast featuring Dr. MacNay and Hoffman, Hoffman stated that "Dr. MacNay, our medical director, is seeing the most seriously ill patients." Dr. MacNay charged $10,000 for a course of intravenous treatment with T-Up. In February 1998 the Virginia Board of Medicine revoked Dr. MacNay's license because he unlawfully had directed an unlicensed person in his office to administer T-Up intravenously in the treatment of cancer. This was after a patient had died, in May 1997, in Dr. MacNay's office during such a treatment.

The Agency found that the appellants' recommendations for intravenous administration of T-Up constituted an implied representation that intravenous administration of the product is lawful. *See Golt v. Phillips*, 308 Md. 1, 9, 517 A.2d 328, 332 (1986) (landlord's offer to lease unit in multiple dwelling impliedly represents that the building is licensed as required by law). Deoul does not challenge that there was an implied representation.

At the hearing, however, Deoul sought to show that intravenous application of T-Up was legal. For that purpose he tendered the affidavit of Karen A. Weaver, a registered pharmacist and a member of the Illinois Bar whose field of legal concentration is FDA law.

The relevant part of her affidavit reads as follows:

> "I have thoroughly researched case law, the Federal Food, Drug, and Cosmetic Act, as Amended, the Dietary Supplement Health and Education Act of 1994, the Code of Federal Regulations and allied legal articles and publications to identify specific regulations which would prohibit the intravenous use of a dietary supplement consisting of ingredients including aloe vera and cesium chloride. The [FDA] has not promulgated any regulations, statutes, or laws *specifically barring* the intravenous administration of aloe vera, cesium chloride, or the primary ingredient in T-Up in human beings for any claimed use whatsoever."

(Emphasis added).

The ALJ excluded this affidavit because she did not want "to accept the statement of an attorney on a legal issue in this case."

This ruling was clearly within the ALJ's discretion. "As a general rule, expert witnesses may not give opinions on questions

of law except for those concerning the law of another jurisdiction." *Franch v. Ankney*, 341 Md. 350, 361, 670 A.2d 951, 956 (1996). Under this rule, federal law is part of the domestic law of the forum state. 2 *McCormick on Evidence* § 335, at 414 (J. Strong 4th ed. 1992); *compare* Md. Code (1974, 1998 Repl. Vol.), § 10-501 of the Courts and Judicial Proceedings Article (indicating by omission the lack of necessity for statutory authorization, via the Maryland Uniform Judicial Notice of Foreign Law Act, for a Maryland court judicially to notice Acts of Congress).

Deoul, however, argues a lack of basic fairness. He points to the affidavit of an FDA-employed pharmacist, Elaine Abraham, which was offered by the Division and admitted by the ALJ and which stated that "[t]he FDA has not *approved* the intravenous administration of aloe vera, cesium chloride, or T-Up in human beings." (Emphasis added). By admitting this affidavit while excluding that of Ms. Weaver, Deoul argues, the ALJ created a situation of "basic unfairness" by considering only the evidence presented by the Division. *See Schultz v. Pritts*, 291 Md. 1, 7, 432 A.2d 1319, 1323 (1981) ("In general, while administrative agencies are not bound by the technical common law rules of evidence, they must observe the basic rules of fairness as to parties appearing before them."). In this Court Deoul argues that the Abraham affidavit was admitted to create an inference that intravenous administration was illegal but that the ALJ would not

admit the Weaver affidavit to support an inference that such use was legal.

There is no unfairness and no error. In its final order the Agency concluded that, before the ALJ, the Division "ha[d] not shown that the administration of [appellants'] products intravenously is illegal." The Agency did find, based on the Abraham affidavit, that intravenous administration had not been *approved* for human beings by the FDA. That finding is not in issue on this appeal. That finding is one of historical fact based on public record and is not a legal conclusion.

The Agency concluded that the appellants' implied representations as to the legality of intravenous administration had violated CL § 13-301(1) because of the lack of substantiation by the appellants that that form of treatment was legal. Other than by tendering Weaver's affidavit opinion on domestic law, Deoul has not undertaken to brief and analyze federal law to demonstrate that intravenous application of T-Up is legal. Further, Weaver's carefully phrased conclusion that there is no federal law "specifically barring" intravenous administration of aloe vera or cesium chloride has no apparent relevancy, given that the regulatory system enforced by the FDA prohibits distribution of a new drug absent prior approval. *See Zeneca, Inc. v. Shalala*, 213 F.3d 161 (4th Cir. 2000). For purposes of this case, T-Up and

cesium chloride are new drugs under federal law. See Part IX, *infra*.[7]

IX
(Issue 4)

Deoul challenges a provision in the Agency's final order requiring the appellants affirmatively to disclose that the intravenous use of aloe vera is illegal. Deoul bases his argument solely on the previously quoted statement in the Agency's findings of fact and conclusions of law that the Division "has not shown that the administration of [appellants'] products intravenously is illegal."

The challenged provision in the order is premised on a legal conclusion reached by the Agency based on its interpretation of the Federal Food, Drug and Cosmetic Act (FDCA), as amended, 21 U.S.C. § 301 *et seq*. The legal issue came before the Agency on exceptions by the Division to the ALJ's conclusion that appellants' representations about the legality of intravenous use did not violate CL § 13-301(9) ("Deception [etc.] with the intent that a consumer rely on the same ...."). The Agency concluded that intravenous use of sterile T-Up was a "drug" as defined in 21 U.S.C. § 321(g)(1)(B), because drugs are "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man[.]" The Agency further concluded that intravenously

[7]As we also shall see in Part X, *infra*, appellants knew that intravenous administration of T-Up was illegal.

administered T-Up fell within the statutory definition of a "new drug" and thus could not be distributed in interstate commerce unless an application to the FDA had been submitted and approved. 21 U.S.C. § 355(a).

A "new drug" is defined as "any drug ... the composition of which ... is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the condition prescribed, recommended, or suggested in the labeling thereof[.]" 21 U.S.C. § 321(p)(1).

> "'"[G]eneral recognition" requires a two-step showing: first ... that there is an expert consensus that the product is effective; and second, that the expert consensus is based upon "substantial evidence" .... Substantial evidence does not consist of the expressed opinions of experts hired to testify on behalf of one party or the other. Instead, it consists of adequate and well-controlled studies that must be generally available to the scientific community.'"

United States v. Undetermined Quantities of Articles of Drug, 145 F. Supp. 2d 692, 700-01 (D. Md. 2001) (citations omitted). *See also United States v. 50 Boxes*, 909 F.2d 24 (1st Cir. 1990) (headache product that had been on the market for thirty-five years was deemed to be a "new drug" because there were no scientific investigations to demonstrate the requisite general recognition).

The governing regulations under the FDCA expressly state that "[t]he newness of a drug may arise by reason ... of:

....

> "(4) The newness of use of such drug in diagnosing, curing, mitigating, treating, or preventing a disease, or to affect a structure or function of the body, even though such drug is not a new drug when used in another disease or to affect another structure or function of the body.
>
> "(5) The newness of a dosage, or method or duration of administration or application, or other condition of use prescribed, recommended, or suggested in the labeling of such drug, even though such drug when used in other dosage, or other method or duration of administration or application, or different condition, is not a new drug."

21 C.F.R. § 310.3(h). *See, e.g., Hoffman v. Sterling Drug, Inc.*, 485 F.2d 132, 137-38 (3d Cir. 1973) (holding that where a drug had been approved by the FDA for the treatment of malaria, subsequently offering the same drug to the public for use in the treatment of lupus rendered it a "new drug" and required prior FDA approval); *United States v. Articles of Drug*, 442 F. Supp. 1236, 1243 (S.D.N.Y. 1978) (finding that an epilepsy drug in the form of time release capsules was a "new drug," notwithstanding the fact that the same drug "in single dosage form [was] generally recognized as safe and effective").[8]

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[8]There are striking similarities in the proof required for "general recognition" under the FDCA and substantiation for medical product advertising claims under the FTC Act. Anecdotal evidence and testimonials do not rise to the level of substantial evidence. *See, e.g., United States v. Articles of Food & Drug*, 444 F. Supp. 266, 274 (E.D. Wis. 1978) ("The testimony of lay witnesses as to the existence of cancer and the safety and efficacy of an alleged cancer treatment based on their personal experience ... is entitled to no weight[.]"). What are needed are "'adequate and well-controlled investigations' [that] satisfy a host of technical scientific requirements, including a 'valid comparison with a control' such as an 'active treatment trial' that includes

(continued...)

Against the foregoing background, we interpret the Agency's statement that the Division "has not shown" the illegality of intravenous application to mean that factual evidence of the lack of approval, in and of itself, does not prove illegality. It is the combination of the Agency's legal conclusion that appellants' products, intravenously administered, are new drugs with the lack of approval that creates the illegality and justifies the provision in the final order.

X
(Issue 5)

Deoul submits that affidavits from eighty of the Company's customers which he offered in evidence were excluded erroneously by the ALJ.[9] The affidavits deal principally with the customers' favorable experiences with the Company's products and its employees.

On the eighteenth day of the hearing the ALJ and the parties addressed how to handle the eighty affidavits. The ALJ ordered the Division to state in writing, affidavit by affidavit, its specific objections. That was done, and Deoul responded in writing to the

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[8](...continued)
'randomization and blinding of patients or investigators' (double blind studies)." *United States v. 50 Boxes*, 909 F.2d 24, 26 (1st Cir. 1990) (citations omitted).

[9]Four of the consumers had medical or health training of some kind, but Deoul does not contend in this Court that that characteristic of the affiants requires a separate analysis from the mass of lay affiants.

Division's objections. On the twenty-fifth day of the hearing, after considering the written and oral arguments of the parties, the ALJ ruled that the affidavits "have not met the initial test of relevance."

The ruling was correct because the affidavits do not show support for appellants' representations that meets the Standard. Even though it was within the discretion of the ALJ to admit the affidavits into the record, the decision to require strict relevancy was not an abuse of discretion on the facts here. The fact that eighty consumers were satisfied with the products does not necessarily mean that the products were effective. *See, e.g., FTC v. Pantron I Corp.*, 33 F.3d 1088, 1098 (9th Cir. 1994) (finding consumer satisfaction evidence to be suspect because it does not take the placebo effect into account), *cert. denied*, 514 U.S. 1083, 115 S. Ct. 1794, 131 L. Ed. 2d 722 (1995).

Analogy to Maryland Rule 5-701 supports the exclusion of the affidavits. That rule limits lay testimony "in the form of opinions or inferences ... to those ... which are (1) rationally based on the perception of the witness ...." A number of the proffered consumer affidavits contain statements that either implicitly or explicitly credit T-Up or cesium chloride with curing diseases. These customers, however, cannot give medical opinions. These customers essentially offered a conclusion based on the fact that they felt better after beginning a regimen of T-Up or cesium

chloride, and the ALJ was well within her discretion to exclude that testimony. "'When ... the witness is "pulling together" his observations and is therefore testifying to conclusions, the trial judge should not admit such testimony.'" *Goren v. United States Fire Ins. Co.*, 113 Md. App. 674, 687, 688 A.2d 941, 947 (quoting J.F. Murphy, Jr., *Maryland Evidence Handbook* § 603(B), at 328 (1993)) (alteration in original), *cert. denied*, 346 Md. 27, 694 A.2d 949 (1997).

Further, prior to the challenged ruling, the ALJ already had heard from eleven or twelve customer witnesses called by the appellants. Moreover, appellants previously had placed in evidence a "Success Stories" exhibit. This was a log of favorable communications, principally telephonic, received by the Company in which it listed the customer's name and telephone number, the ailment(s), the customer's description of the results of using the Company's product, and the dosage taken. One hundred eleven customers were listed on the "Success Stories" log. In view of the amount of evidence that already had been received concerning customers' opinions, the ALJ was entitled to cut off anecdotal evidence from eighty more consumers. *See State v. Allewalt*, 308 Md. 89, 110, 517 A.2d 741, 751-52 (1986) (considering relevance of proffered evidence includes as a factor the time required to try properly an expanded case).

Deoul argues to us that the affidavits are relevant to the civil fine, because they evidence, he submits, his good faith and the lack of customer contact directly with him. Deoul, however, has not directed us to any portion of the record, and we have found none, where Deoul argued that the affidavits should be admitted for that limited purpose. Indeed, Deoul filed no exceptions with the Agency to the ALJ's proposed findings and conclusions, even though the affidavits would have served as convenient proffers in seeking an overturning by the Agency of the ALJ's exclusion of the affidavits.

Also significant is that, although the Agency made a specific finding that appellants lacked good faith, that finding did not involve Deoul's or Hoffman's subjective belief in the efficacy or safety of the products. On the good faith issue the Agency said that:

--appellants "knew from the outset of their business that the intravenous administration of their products was illegal in the United States, yet they made representations of legality without any reasonable basis;"

--appellants "worked closely with Dr. MacNay and referred desperately ill consumers to him for [intravenous] procedure;"

--Hoffman "essentially obtained a mail-order Ph.D. degree, and then used this false credential in every advertisement and in every contact with consumers;" and

--appellants "knew that they could not legally claim that their products were effective in treating or curing diseases in humans."

In the audio tape Hoffman acknowledged that aloe vera may not be administered intravenously in the United States, saying that "the FDA has looked at aloe vera quite extensively and ... said '... you can let people drink aloe vera. It's a natural substance, it's a health food. But you can't inject it into people.'"

Deoul does not dispute that the Company referred patients to Dr. MacNay or that Hoffman had no Ph.D. degree. The Agency's fourth finding simply recycles appellants' failure to conform to the Standard for substantiation and adds that appellants knew of the lack of legal substantiation. Knowledge by an alleged violator of the illegality of a practice may be found based either on actual knowledge or on a finding that the violator should have known of the illegality. *See State of Md. Cent. Collection Unit v. Kossol*, 138 Md. App. 338, 349, 771 A.2d 501, 507 (2001) (citing *FTC v. Amy Travel Serv., Inc.*, 875 F.2d 564, 573-74 (7th Cir.), *cert. denied*, 493 U.S. 954, 110 S. Ct. 366, 107 L. Ed. 2d 352 (1989)). Here, there is no defense of advice of counsel with respect to the legally required substantiation for advertising disease cures and, indeed, Deoul holds a law degree. Consequently, the exclusion of the eighty consumer affidavits had no prejudicial effect on the finding of a lack of good faith.

As part of his argument that the excluded affidavits were relevant to the civil fine, Deoul, by record reference, directs us to fourteen of the eighty consumer affidavits in which the affiants state that they had no dealings with Deoul. The argument is that this shows that Deoul was not an active participant in the Company's representations. When one considers that there were thousands of customers who were purchasing the Company's products, the lack of contact with Deoul by fourteen customers is of such slight relevance on the issue of the extent of Deoul's participation in the deceptive advertising as to render the error, if any, non-prejudicial.

XI
(Issue 6)

Next, Deoul complains about case management by the ALJ. From among the eighty affidavits excluded for lack of relevance, Deoul identifies thirteen affidavits that he represents are from customers whom Deoul named on his original witness list. When the ALJ reduced Deoul's witness list she advised that affidavits could be submitted. Deoul argues for reversal because the ALJ thereafter excluded the thirteen affidavits. This issue arises out of the background set forth below.

Deoul initially wanted to call as many as thirty-seven witnesses to testify in person, and on his original witness list he identified thirty persons. Before testimony was taken on the second day of the hearing, October 27, 1998, the ALJ advised the

parties that, absent some other acceptable proposal, she was disposed to limit the number of consumer witnesses to eight per side. She said: "Other witnesses' evidence may be submitted by affidavit." At the conclusion of proceedings on that same day the ALJ reiterated a proposed limit of eight, absent the parties' submitting some better solution by the next morning. Deoul inquired if he would be permitted to provide affidavits from those individuals on his witness list who would not be permitted, under the ruling, to testify in person, and the ALJ replied, "Oh, absolutely, yes."

The colloquy continued, during which Deoul said that he had already reduced his list of witnesses to twenty. He then said: "[I]f you do hold us to eight, I have to have a proffer on the record of what these people were going to say ...." The ALJ replied:

> "Well, I am going to accept any affidavits that you would like to present, and in terms of, you know, you're referring to a proffer, I am not going to hear proffers on 15 witnesses tomorrow morning."

Deoul interprets the above-described case management arrangements as a commitment on the part of the ALJ to accept into evidence affidavits from any person on Deoul's witness list who did not testify in person, without regard to the relevance of the content of the affidavits. The ALJ's response, however, can be interpreted to mean that the affidavits would serve first as proffers and that, in anticipation of objections by the Division,

the ALJ was not going to hear arguments on the affidavits' admissibility the next morning. The latter is the more reasonable interpretation of the arrangement.[10]

In any event, on the next morning Deoul argued that he should be permitted to call more than eight live witnesses because he wished to present a live witness to describe favorable results from the Company's products with respect to each of the diseases involved in the Company's claims. The ALJ modified her tentative ruling and limited each side to twelve live consumer witnesses.

The appellants began presenting their case on the ninth day of the hearing, November 18, 1998. Between January 21 and February 23, 1999, they called eleven customer witnesses, whose examinations consumed the fifteenth, eighteenth, nineteenth, and twentieth hearing days. On the twenty-second hearing day, near the conclusion of the direct examination by Deoul of Dr. Heggers, the witness stated that he had been diagnosed with prostate cancer and that he began taking an aloe product, after which his prostate serum assay had remained stable for the six months preceding his testimony. The ALJ then stated her intention to consider Dr. Heggers as a twelfth consumer witness and inquired whether Deoul

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[10]As described in Part X, *infra*, the ALJ required the Division to set forth in writing any objections that it might have to the substance of any affidavit proffered by Deoul, including the thirteen from witness list customers, and Deoul responded in writing. Oral argument on the objections was held on the twenty-fifth day of the hearing.

intended to call some other consumer witness. Deoul replied, "I frankly think another consumer witness in this case at this late stage simply is not necessary." Accordingly, any objection to the limitation on the number of consumer witnesses has been waived. Now, in this Court, Deoul argues that additional consumer testimony should have been received in affidavit form.

Even if we consider that the ALJ changed her mind by not blindly accepting affidavits from individuals on Deoul's original witness list, she had the power to change her mind and did not abuse her discretion by doing so under the circumstances. We repeat that the affidavits were not strictly relevant due to their failure to meet the Standard. Further, from the standpoint of what bearing they might have on good faith, as it bore on a civil penalty, the ALJ reasonably could conclude that the customer witnesses and "Success Stories" exhibit already had demonstrated that there were, among the Company's customers, true believers in the efficacy of its products. The ALJ, within her discretion, could conclude that it would be cumulative to place in the record affidavits from customer witnesses.

XII
(Issue 7)

The final argument advanced by Deoul is that the Agency lacks substantial evidence to find him personally liable for the violations. In *Hartford Accident & Indem. Co. v. Scarlett Harbor Assocs. Ltd. Partnership*, 109 Md. App. 217, 674 A.2d 106 (1996),

aff'd, 346 Md. 122, 695 A.2d 153 (1997), this Court held that "a CPA violation is in the nature of a tort action[.]" *Id.* at 265, 674 A.2d at 129. Officers of a corporation may be individually liable for wrongdoing that is based on their decisions. *See Metromedia Co. v. WCBM Md., Inc.*, 327 Md. 514, 519-22, 610 A.2d 791, 794-95 (1992). And, where a corporate officer is present on a daily basis during commission of the tort and gives direct orders that cause commission of the tort, the officer may be personally liable. *See Levi v. Schwartz*, 201 Md. 575, 583, 95 A.2d 322, 327 (1953). If an officer "'either specifically directed, or actively participated or cooperated in'" the corporation's tort, personal liability may be imposed. *St. James Constr. v. Morelock*, 89 Md. App. 217, 223, 597 A.2d 1042, 1045 (1991), *cert. denied*, 325 Md. 526, 601 A.2d 100 (1992) (citation omitted). Deoul submits that he was primarily a financial backer who had so little active participation in the Company's day-to-day business that, under the foregoing principles, the proof against him fails the substantial evidence test. We disagree.

Scott Van Horn (Van Horn), a former "customer service representative" for the Company, testified by deposition that both Deoul and Hoffman were selling T-Up from two locations in the Baltimore metropolitan area before the Company was incorporated. When the Company was formed in November 1996 the organizational minutes recited the transfer to the Company by Deoul and Hoffman of

"inventions, developments, ... technology, trade secrets and all other confidential and proprietary information relating to certain aloe vera and cesium products, developed and owned, jointly and severally, by Neal Deoul and Allen J. Hoffman."

The Company's office manager, Jeananne Marie Hammond (Hammond), testified by deposition. She had been interviewed by both Hoffman and Deoul when she was applying for that position. She testified that portions of the desk reference manual that described various diseases, followed by the recommended dosage of the Company's products, had been prepared by Van Horn who had obtained the disease descriptions from medical textbooks kept in the Company's office. Deoul and Hoffman had decided which medical textbooks to purchase, and the two of them and Van Horn reviewed the textbooks after purchase. Hammond also said that Deoul handled most of the business decisions, including negotiations with other organizations that wanted to sell T-Up. There were at least two main, independent distributors for the Company's products, one of whom was in Chile. Hammond recalled one occasion in approximately November of 1997 when Dr. MacNay came to Baltimore to meet with Deoul and Hoffman. She said that, within the Company, it was Deoul's responsibility to order the tapes containing Hoffman's lecture and that thousands of them had been distributed. When Hammond was asked, "Who was it at T-Up that discovered the medical

uses of cesium chloride?", she replied, "Neal Deoul."[11] According to Hammond, Hoffman and Deoul jointly participated in the decision to place a disclaimer sticker on the brochure that accompanied product shipments.

Van Horn testified that during his employment with the Company, he was supervised by Hammond, Hoffman, and Deoul. Van Horn testified that Deoul was in the office "five days a week except he travels a lot."

Particularly damaging to Deoul's argument is the testimony of one of the Division's consumer witnesses, Robert Knudsen (Knudsen). Knudsen is an academic administrator in the athletic department at California State University, Fresno. He was told by a business associate about T-Up and furnished with Deoul's home telephone numbers. On behalf of a friend, James Darden, Knudsen telephoned Deoul and made notes of the conversation. Deoul stated that he had a Ph.D., that T-Up was 100 times more powerful than aloe vera, that it stimulated T-cell growth, that cesium chloride raised the pH level, that cancer cells could not live in high pH, and that cesium chloride killed only cancer cells. Deoul told Knudsen that cesium chloride would kill cancer cells "every time" and that it would reduce the size of a tumor from thirty-five to seventy-five

[11]Even if Hammond's belief is mistaken, the fact that she held that mistaken belief is some evidence that Deoul was not a mere passive investor in the Company.

percent. Deoul also told Knudsen that Hoffman had a Ph.D. in biochemistry and that he had been a cancer researcher.

Thereafter Knudsen spoke by telephone with Hoffman who told Knudsen the same things that Deoul had told Knudsen.

On a third occasion a telephone conversation took place between Deoul, Darden, and Knudsen in which Deoul repeated substantially the same representations. In addition, Deoul told them that approximately fifty doctors in nineteen centers were using the Company's process with success. The process involved an intravenous administration of the Company's products. Deoul recommended that the intravenous protocol could be administered by a Dr. MacNay in Virginia.

We conclude that substantial evidence supports Deoul's personal liability for the civil fine.

For all of the foregoing reasons, we affirm.

JUDGMENT OF THE CIRCUIT COURT FOR BALTIMORE COUNTY AFFIRMED.

COSTS IN THIS COURT TO BE PAID BY APPELLANT, NEAL DEOUL.