

STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

BOARD OF MEDICAL EXAMINERS,)
)
 Petitioner,)
)
vs.) CASE NO. 76-1457
)
B. G. GROSS, M. D.,)
)
 Respondent.)

)

RECOMMENDED ORDER

Pursuant to notice, the Division of Administrative Hearings, by its duly designated Hearing Officer, K. N. Ayers, held a public hearing in the above styled case on December 1, 1976 at Orlando, Florida, and on December 2, 1976 at Miami, Florida.

APPEARANCES

For Petitioner: Michael Schwartz, Esquire
Ellis Building, Suite 201
1311 Executive Center Drive
Tallahassee, Florida 32301

For Respondent: Harvey Richman, Esquire
407 Lincoln Road, Suite 11-A
Miami, Florida 33139

RECOMMENDED ORDER

By complaint filed July 17, 1976, the Florida State Board of Medical Examiners seeks to revoke, suspend or otherwise discipline the license of B. G. Gross, M. D. As grounds therefor it is alleged that at divers times between September, 1973 and January, 1975, Respondent, in violation of Section 468.1201(1)(k), F.S., injected silicone into the bodies of Diane A. Carter, Ann Kern, Dorothy Belcher, and Vicki Diaz, after executing an affidavit with Dow-Corning (Dow) that said drug, which was prohibited by Food and Drug Administration Regulations from being transported in interstate commerce for injection into humans, would not be injected into humans; that by injecting said liquid silicone so received from Dow, Respondent committed a fraud in the practice of medicine in violation of Section 458.1201(1)(b), F.S.; and that such unauthorized use of silicone constitutes deleterious conduct or practices harmful to the public and constitutes a violation of Section 458.1201(1)(h), F.S.

The parties stipulated that B. G. Gross, Respondent, is licensed to practice medicine in Florida by the State Board of Medical Examiners and that Gross was not, during the times here involved, listed as a Claimed

Investigational Exemption, as an investigator for use of liquid silicone with the U.S. Food and Drug Administration.

Thereafter eight witnesses were called by the Petitioner, Dr. Gross testified in his own behalf and 23 exhibits were admitted into evidence. The parties further stipulated that the testimony of Dr. Perry A. Sperber, M.D., be taken by deposition and his deposition be admitted into evidence as Exhibit 24.

FINDINGS OF FACT

1. B. G. Gross, M.D. is licensed by the Florida State Board of Medical Examiners and the Hearing Officer had jurisdiction over the Respondent and the offenses alleged. Gross is certified by the American Board of Dermatology.

2. Amending Title 21 U.S. Code in 1962 led to the Food and Drug Administration (FDA) curtailing the interstate transportation of liquid silicone by declaring the use of liquid silicone by injection for soft tissue augmentation to be an experimental procedure. This made liquid silicone, intended for this use, a "new drug" as defined in 21 U.S.C. 321(p). Thereafter shipment of such drug could be made only to the seven named clinical investigators (later augmented to eight) approved by FDA for experimenting, under controlled and regulated procedures, on the use of injectable silicone in humans. Injections for mammary augmentation was not included in the approved use.

3. Between 1967 and 1969 Gross engaged in correspondence with Dow to obtain liquid silicone from Dow suitable for injecting. Specifically Gross attempted to obtain Dow-Corning 360 Medical Fluid and be denominated a clinical investigator authorized to experiment with injectable silicone by injecting into humans.

4. In 1967 following the commencement of this correspondence Gross executed an affidavit that he would not inject any Dow-Corning 360 Medical Fluid "hereafter received by me from Dow" into humans but would use same only for experimenting on animals, and Dow forwarded to him one pint of such silicone.

5. Having no further success obtaining silicone shipped to him in Miami from Dow, Gross investigated the possibility of obtaining Dow 360 in Bermuda but here too he was unsuccessful. A subsequent attempt to be designated as a clinical investigator authorized to experiment with injectable silicone designated MDX-4-4011 fluid was also unsuccessful. This latter fluid differs from Dow 360 principally in being shipped in sterile ampules of 1cc and 5cc capacity and being subject to stricter manufacturing controls.

6. Breast augmentation has been performed by some practitioners for many years. The process was greatly discredited in the 1920's when the medical profession became aware of the disastrous results associated with the use of paraffin for breast augmentation.

7. The most experienced practitioner in this discipline today is probably Dr. Sakurai of Tokyo, Japan, who started such work in the mid-1940's. Subsequent to the discovery of silicone Sakurai used silicone to which he added some undisclosed organic oil to create an irritative reaction which would wall off the injected silicone to keep it immobile.

8. The Sakurai Corporation was incorporated in California in 1962 to market this product and in March, 1963 was granted an investigative exemption to

permit the use of this product for breast tissue augmentation. This investigational exemption was terminated on May 17, 1963 because the sponsor failed to submit requested data on manufacturing controls, animal toxicity and labeling.

9. Prior to liquid silicone being classified as a "new drug" in 1963 Dow-Corning 360 Medical Fluid was available from drug supply houses and had been used by practitioners in this country as well as in Europe and Japan for breast augmentation.

10. Although silicone is inert, non-toxic, water repellent and does not stimulate immunologic reaction as do many other materials implanted in the body, prior to the time the FDA classified liquid silicone as a "new drug" many scientists had concluded that its use was contraindicated for breast augmentation.

11. Literature forwarded to Gross by Dow (Exhibit 11) when he inquired about the use of liquid silicone contained the following quotations:

"Dow Corning does not feel that this material can be recommended for human injection."

"... The FDA called a halt to the use of injectable silicone by classifying silicone for injection into humans as 'new drugs'. The agency prohibited the use of silicone on humans until specific research had been undertaken to determine its safety and effectiveness under a claimed investigational exemption."

"Recent and preliminary experimental evidence has indicated that silicone fluids may be transported to far removed tissues and organs, but much more work must be completed before definite conclusions are reached."

"Cautions Warranted. The present suggested clinical misuses of silicone fluids are as follows:

1. Mammary augmentation.*

*Although the results in a selected group of cases injected properly and conservatively (not over 5 to 10 cc at any one time) have been encouraging, the continued use in this respect, since the filing of the IND with the FDA, has been postponed until a long-term follow-up has been established and these earlier results have been completely evaluated."

"The contention that a causal relationship may exist between breast implantation and the subsequent development of mammary cancer cannot be answered definitely at this time."

"The Federal Food and Drug Administration has stated that the injection of silicone fluids either in the pure form or as mixtures with other materials, con-

stitutes a 'drug use'. Therefore the fluid used in this manner is a 'new drug' and specific investigative procedures must be followed to establish its safety and effectiveness."

"Furthermore, it is well to note that the use of silicone fluid for breast augmentation has for many years been considered unwise by those clinical investigators most experienced with this material, because the volumes required are far in excess of those which were found safe for local administration. More importantly, examination of breasts for natural diseases is made difficult or impossible after injection with silicone fluid because of the distortion of the normal breast architecture which occurs."

12. Dr. Gross has been interested in silicone injections since he was taking his residency in California in 1962. His testimony that he purchased some 5 or 10 gallons of Dow 360 Medical Fluid from a medical supply house in California in 1962 (before Dow took it off the market) in 500 cc (one pint) bottles (the standard size in which this material was packaged) subsequently poured these pint bottles into one gallon Chlorox bottles he had washed out, and transported this material to Florida where he kept these jars in his garage for several years before using it for injection, is simply not credible.

13. Although denied by Gross, more than one of the witnesses testified that Gross told them the silicone he injected contained linseed oil. This would indicate that the silicone used by Gross possibly came from the Sakurai Corporation and was acquired by Gross on the "bootleg" market.

14. Gross' interest in injectable silicone led him, according to his own testimony, to read all medical literature on the subject he could locate. In Exhibits 12, 13, and 18 with which Gross claimed familiarity the following appears:

"Abuse of the material must be prevented because most problems and complications from improper use of liquid silicone are difficult to treat since the fluid cannot be retrieved from the tissues once injected."

"During the past ten years, a high proportion of women who live here have had some type of 'liquid silicone' injection, despite intensive educational campaigns by physicians, hospitals, and the Medical Society. One estimate is that at least 12,000 women have had 'bootleg silicone injections' mostly in the breast area, and that at least one percent of them developed some type of problem each year."

"...the more common localized problems, such as: infection, migration, cyst formation, deep tissue silicoma formation, and degrees of skin involvement from pigmentation to gangrene."

"Although the problems we see in clinical practice in Las Vegas are said by Dow Corning representatives to be a result of injections of some type of 'liquid silicone' other than their 'medical grade 360', we have seen a number of the problems definitely from cases originally injected with 'medical grade 360' legitimately released for research several years ago."

"The dream of a safe and simple method of correction of contour defects with injection of liquid silicone has not materialized despite ten years of intensive research by qualified investigators."

"Examples of migration of silicone from the breasts into the axilla and chest wall are illustrated. At present, injection of silicone for purposes of breast augmentation is prohibited by the Food and Drug Administration. Precise information regarding the purity, type, and quantity of silicone injected is therefore difficult to obtain."

"Since the injected silicone is relatively dense and often produces palpable masses, routine mammograms are suggested in patients with a history of silicone injections in the breasts. This examination could serve as a base line for comparison with subsequent studies, should malignant tumor be suspected at a later date."

15. Dr. Gross injected liquid silicone into the breasts of Diane A. Carter, Dorothy Belcher, Ann Kern and Vicki Diaz, in addition to other patients not named in the Complaint. His normal practice was to inject 80 cc of silicone into each breast on the first visit. Many of his patients for breast augmentation returned for three treatments.

16. The complaining witnesses all learned of Gross through friends and most of them first visited Dr. Gross' office in company with a friend.

17. In response to inquiries about the process Gross assured the patients that following the injection of silicone their breasts would be beautiful. Although Gross later commenced using a release form which he had his patients for mammary augmentation sign, "because my lawyer thought it a good idea," even then he did not fully explain the potential hazards of silicone injection to these patients. The patients receiving treatment before the advent of the release (Exhibit 9) likewise were not fully advised of the hazards involved with silicone injections.

18. Gross advised his patients that if lumps formed they could be broken up by finger pressure or squeezing which would break up the silicone into small globules.

19. Initially all complaining witnesses were pleased with the result of the silicone injection. However they developed tenderness, inflammation and lumps in their breasts some months after their injections. None of them returned to Gross for treatment but instead went to family doctors (or plastic surgeons) who referred them to plastic surgeons for consultation.

20. All of these witnesses were advised that the silicone could be removed only by mastectomy and that such drastic procedure was not recommended at the present time with the present discomfort they are suffering. No other method of removing injected silicone is presently available.

21. Dr. Gross testified that he used only Dow Corning Medical Grade 360 silicone, although, since he told at least two of the witnesses in his office that the silicone used contained linseed oil, it is likely that he used both Dow 360 and other silicone.

22. At the hearing Dr. Gross produced a nearly full bottle of Dow Medical Grade 360 silicone which was the bottle he received from Dow after executing the affidavit that he would not use that material for injection into humans. The missing silicone, according to Gross, was given to one of the dermatologists in his office. The amount removed from the 500 cc bottle, approximately 100cc, was not enough for Gross to have done a breast augmentation on one patient.

23. No evidence was adduced that Gross used the Dow Medical Grade 360 received as a result of his affidavit for injection into humans.

24. The Food and Drug Administration has no power to control a doctor engaged in the practice of medicine. Those authors quoted above are technically incorrect when they say the FDA has made the use of liquid silicone unlawful for mammary augmentation. By declaring injectable silicone a new drug the FDC has made it illegal to ship or transport this material in interstate commerce except to those licensed investigators approved to conduct clinical investigations. As stipulated by the parties, Gross was not a licensed investigator authorized to inject liquid silicone into humans.

25. If Gross' testimony is true that he acquired the silicone injected into the breasts of the four complaining witnesses in 1962 while he was a resident in California, this material was moved from California after the effective date of 12 U.S.C. 355, viz Oct. 10, 1962.

26. Exhibit 17, Curriculum Vitae of Bernard G. Gross, shows that Gross was resident in dermatology, Veterans Administration Hospital, Los Angeles, California 1962-1963; Chief Resident in dermatology, Boston City Hospital, Boston, Mass. 1963-1964; and Instructor, Department of Dermatology, University of Miami School of Medicine, Miami, Florida 1964-1965.

CONCLUSIONS OF LAW

27. Section 458.1201, F.S., provides in pertinent part:

"1. The Board shall have authority to deny an application for a license or to discipline a physician who, after hearing, has been adjudged unqualified or guilty of any of the following:

* * *

b. Making misleading, deceptive, untrue, or fraudulent misrepresentations in the practice of medicine;

* * *

h. Engaging in any unethical, deceptive or deleterious conduct or practice harmful to the

public, in which proceeding proof of actual inquiry need not be established.

* * *

k. Violating a statute or law of this state, any other state, or of the United States (without regard to its designation as either felony or misdemeanor), which statute or law relates to the practice of medicine or in part regulates the practice of medicine."

Respondent is charged with fraud in the practice of medicine resulting from signing an affidavit that he would not use Dow Corning 360 Medical fluid received as a result of his affidavit, for injection into humans. He was not charged with fraud resulting from failure to fully inform patients of the risks associated with liquid silicone injections. Absent proof that the silicone obtained from Dow as a result of Gross' affidavit was used for injection in humans, a violation of Section 458.1201(1)(b). F.S. above quoted has not been proved.

28. With respect to the allegation that Gross violated a statute of the United States, viz 21 U.S.C. 355(i), the wording of the Complaint must be carefully considered to ascertain exactly with what Gross has been charged.

21 U.S.C. Section 355 provides in pertinent part:

"(a) Approval required. No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to Subsection (b) is effective with respect to such drug."

29. As noted above, liquid silicone has not received such approval from FDA.

30. 21 U.S.C. Section 355(i) provides an exception to the above for the shipment of new drugs for investigational research performed by approved investigators. Respondent has stipulated that he is not a licensed investigator and therefore does not fall within this exception.

31. Counts I-IV also allege that licensee has engaged in conduct prohibited by 21 U.S.C. 331(d). The facts alleged are that he injected liquid silicone in Diane Carter, Dorothy Belcher, Ann Kern and Vicki Diaz, that liquid silicone is a new drug, the introduction of which into interstate transportation is restricted to others than licensee, and that he thereby violated 21 U.S.C. 355.

21 U.S.C. 331(d) prohibits:

"d. The introduction or delivery for introduction into interstate commerce of any article in violation of section 404 or 405 (21 U.S.C. 344 or 355)."

32. In order to get the liquid silicone used by Gross for the mammary augmentations here involved, from California, where it was allegedly purchased, to Florida, where it was used, it had to be introduced into interstate commerce. Transporting material across state lines constitutes interstate transportation

and the services of a common carrier are not a necessary part of interstate transportation.

33. Counts I-IV further allege that the acts of Respondent in injecting liquid silicone constitutes deleterious conduct or practice harmful to the public in violation of Section 458.1201(h), F.S., above quoted. As noted in the Findings of Fact, Gross used some 80 cc in each breast on one treatment. A relatively safe amount is 5 to 10 cc. Liquid silicone has the propensity to migrate, and if it gets into the lymph glands it can cause serious problems. One of the more dangerous propensities of injectable silicone into the breasts is the fact that it makes detection of breast tumors more difficult. Since early detection of these tumors is essential for successful treatment, injecting liquid silicone into breasts can constitute a practice harmful to the patient.

34. Using liquid silicone for breast augmentation after studying medical literature pointing out the hazards of such use and stating such use was unlawful, demonstrates an arrogant disregard for accepted medical principles and for the law. It also constitutes a practice harmful to the public.

From the foregoing it is concluded that B. G. Gross, M.D., is not guilty of violation of Section 458.1201(1)(b), F.S., but is guilty of violation of Section 458.1201(1)(h) and (k), F.S. as alleged. It is therefore,

RECOMMENDED that the license of B. G. Gross, M. D. to practice medicine in the State of Florida be suspended for a period of six (6) months.

DONE and ENTERED this 14th day of January, 1977, in Tallahassee, Florida.

K. N. AYERS
Hearing Officer
Division of Administrative Hearings
Room 530, Carlton Building
Tallahassee, Florida 32304