

EXHIBIT G-D

UNITED STATES OF AMERICA
BEFORE THE FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

_____)
In the Matter of)
)
KORANGY RADIOLOGY ASSOCIATES, P.A.,) ADMINISTRATIVE COMPLAINT
trading as BALTIMORE IMAGING CENTERS,) FOR CIVIL MONEY PENALTY
a corporation,)
)
and) FDA Docket: 2003H-0432
)
AMILE A. KORANGY, M.D.,)
an individual.)
_____)

DECLARATION OF MICHAEL P. DIVINE, M.S.

Michael P. Divine declares as follows:

1. I am employed as a Compliance Expert for the Inspection and Compliance Branch, Division of Mammography Quality and Radiation Programs, Office of Health and Industry Programs, Center for Devices and Radiological Health (CDRH), United States Food and Drug Administration (FDA). My work address is 1350 Piccard Drive, Rockville, MD 20850.

2. I received a Bachelor of Science Degree from Emory University in 1976, and a Master of Science Degree in Radiation Science from Georgetown University in 1989.

3. I began working for FDA in 1977 as a field investigator, and, since 1981, I have specialized in the field of radiology. From February 1992 until November 1993, I was a

section chief responsible for various aspects of implementing regulations and policies with respect to x-ray products.

4. Since November 1993, I have been directly or indirectly involved in the planning and implementation of the inspection, compliance, and certification program for mammography facilities under the Mammography Quality Standards Act of 1992 (MQSA), 42 U.S.C. § 263b. I have acted as CDRH's expert on MQSA compliance issues, served as the MQSA compliance instructor, and given presentations on MQSA inspection and compliance issues.

5. In my capacity as a Compliance Expert for the Inspection and Compliance Branch, I have been involved on an ongoing basis in reviewing the compliance status of Korangy Radiology Associates, P.A., trading as Baltimore Imaging Centers (BIC), a mammography facility located at 724 Maiden Choice Lane, Suite 102, Catonsville, Maryland 21228.

Mammography Screening And The MQSA

6. The effectiveness of mammography screening in the detection of breast cancer depends on consistently high-quality mammograms. Breast cancer is a leading cause of death among women in the United States. Because successful treatment of breast cancer often depends on early detection, and because accurate mammograms can detect breast cancer two years before the patient or her doctor could feel a lump, high-quality

mammography screening can greatly enhance the chances for survival. On the other hand, low-quality screening can result in the failure to detect early lesions, delayed treatment, and an increased likelihood of death or mastectomy.

7. The MQSA established nationwide quality standards and a mechanism to ensure that facilities meet those standards. Specifically, the MQSA established uniform mammography standards and a certification process to ensure that only those mammography facilities providing high-quality mammography would remain in operation. Prior to the enactment of the MQSA, there were no national, mandatory standards for ensuring safe and reliable mammography examinations.

8. Under the MQSA, FDA designates and approves private or state agencies to evaluate the performances of mammography facilities and to accredit or re-accredit those that meet certain standards. As relevant to this case, the American College of Radiology (ACR) has been designated and approved by FDA to evaluate the performance of mammography facilities and to accredit or re-accredit those facilities that meet such standards.

9. A facility applies for accreditation from the accreditation body designated by FDA. Once FDA receives notification of the accreditation body's decision to accredit a facility, FDA may issue a certificate to the facility or renew

the facility's existing certificate. A certificate is generally effective for three years after the date that it is issued or renewed. When a facility fails to meet the standards of the accreditation body, the facility is denied accreditation by that body. FDA actively audits the work of the accrediting bodies and remains responsible for bringing enforcement actions against those entities that violate the MQSA.

10. Under certain conditions, facilities may obtain provisional certificates while they demonstrate to their accreditation body that they can comply with that body's standards and obtain accreditation from that body. Receipt of a provisional certificate simply means that the facility has the opportunity to perform mammography and satisfy the requirements for accreditation, in accordance with the requirements of the MQSA.

Baltimore Imaging Centers

11. FDA issued a mammography certificate to Drs. Wityk, Goad, Korangy & Associates, P.A., on May 6, 1999. The certificate, which enabled BIC to lawfully perform mammography, was scheduled to expire on May 6, 2002. By letter dated April 1, 2002, FDA advised Dr. Amile A. Korangy that BIC's mammography certificate was scheduled to expire on May 6, 2002. See Letter from FDA to Amile A. Korangy, M.D. (Apr. 1, 2002), Ex. G-1. The letter also informed Dr. Korangy that the facility could no

longer perform mammography services once its certificate expired. Id.

12. By letter dated April 29, 2002, ACR informed Dr. Korangy that BIC failed to qualify for re-accreditation as a mammography facility. See Letter from ACR to Amile Korangy, M.D. (Apr. 29, 2002), Ex. G-2. As the basis for this decision, ACR found that the mammograms produced by BIC failed to comply with ACR's standards for clinical image quality. Id. ACR also strongly recommended that BIC immediately cease performing mammography examinations. Id.

13. By letter dated May 1, 2002, FDA confirmed to Respondents that BIC had been denied accreditation due to its failure to meet ACR accreditation standards. See Letter from FDA to Amile Korangy M.D. (May 1, 2002), Ex. G-3. Accordingly, FDA advised that it was unable to recertify BIC as a mammography facility and instructed Respondents to cease performing mammography. Id.

14. BIC's certificate expired on May 6, 2002. See Certified Mammography Facility Certificate, Ex. G-4.

15. On July 18, 2002, ACR sent a letter to CDRH notifying CDRH that it was concerned that BIC was performing mammography without a certificate. See Letter from Pamela L. Platt to Joanne Choy (July 18, 2002), Ex. G-5. The letter also stated that, due to this concern, an ACR staff member had placed an

anonymous telephone call to BIC, and that the staff member was told by a BIC employee that BIC was currently performing mammography. Id. The letter concluded with ACR's belief that BIC was conducting mammography without a valid certificate. Id.

16. As a result of the July 18, 2002, letter from ACR, I contacted Elizabeth A. Laudig, a Compliance Officer in FDA's Baltimore District Office, on July 19, 2002. I requested that Ms. Laudig conduct an inspection of BIC to determine whether BIC performed mammography while uncertified.

17. BIC applied for reinstatement of its ACR accreditation by completing a reinstatement application, which was signed by Dr. Korangy. See Reinstatement Application, Ex. G-6. In the application, Dr. Korangy indicated that BIC had corrected its clinical image deficiencies by, among other things, purchasing a new mammography unit. Id. Dr. Korangy transmitted the reinstatement application to ACR by letter dated July 22, 2002. See Letter from Amile A. Korangy to American College of Radiology (July 22, 2002), Ex. G-7.

18. On July 24, 2002, ACR notified FDA that BIC's application for accreditation reinstatement was sufficiently complete for review, and that BIC was eligible for provisional reinstatement.

19. On July 26, 2002, FDA issued a provisional certificate to BIC. See Interim Notice (Provisional Reinstatement), Ex. G-

8. By letter dated July 26, 2002, FDA informed Dr. Korangy that BIC was certified to lawfully provide mammography services. See Letter from FDA to Amile Korangy (July 26, 2002), Ex. G-9.

20. Ms. Laudig, together with Baltimore District Office Investigators Barbara A. Gullick and Walter L. Fava, conducted an inspection of BIC during August 8, 12, 14, 21-22, 2002, and September 3, 5-6, 2002.

21. During that inspection, FDA collected from BIC reports for mammography examinations that BIC performed between May 6, 2002, and July 27, 2002. See Mammography Reports, Ex. G-10.¹ Based on my review of these reports, I have concluded that BIC conducted 192 mammography examinations between and including May 7, 2002, and July 25, 2002. Id. Dr. Korangy read and interpreted the mammograms from at least 116 of these examinations.² The mammograms from the remaining uncertified examinations were read and interpreted by Ifran S. Shafique,

¹Although FDA collected reports for mammography examinations conducted by BIC between May 6, 2002, and July 27, 2002, Exhibit G-10 contains only those reports reflecting examinations that took place between May 7, 2002, and July 25, 2002, the period in which BIC was uncertified to perform mammography.

²The Baltimore District Office investigators did not collect the second page of the mammography reports for the following patients and examinations: K.N. (May 7, 2002); J.S. (May 8, 2002); A.N. (May 9, 2002); R.H. (May 21, 2002); L.L. (June 13, 2002); A.H. (June 20, 200); and P.H. (June 26, 2002). Because the second page is missing from these reports, it is not possible to determine which physician(s) read and interpreted the mammograms from these examinations.

M.D., and Robert J. Hage, D.O. The examinations were performed on the following patients on the following dates, all of which occurred after BIC failed re-certification due to the unacceptable quality of its mammograms:

<u>No.</u>	<u>Patient Initials</u>	<u>Exam Date</u>	<u>Physician</u>
1.	R.C.	5/7/02	Korangy
2.	D.L.	5/7/02	Korangy
3.	A.S.	5/7/02	Korangy
4.	K.N.	5/7/02	
5.	F.P.	5/7/02	Korangy
6.	M.J.	5/8/02	Shafique
7.	P.L.	5/8/02	Shafique
8.	L.S.	5/8/02	Shafique
9.	J.S.	5/8/02	
10.	A.N.	5/9/02	
11.	O.K.	5/9/02	Korangy
12.	R.J.	5/9/02	Korangy
13.	M.H.	5/9/02	Korangy
14.	L.M.	5/10/02	Shafique
15.	M.W.	5/10/02	Shafique
16.	J.D.	5/10/02	Shafique
17.	M.P.	5/10/02	Shafique
18.	S.B.	5/13/02	Korangy
19.	E.W.	5/13/02	Korangy
20.	D.K.	5/13/02	Korangy
21.	B.K.	5/13/02	Korangy
22.	R.F.	5/13/02	Korangy
23.	C.O.	5/13/02	Korangy
24.	S.J.	5/14/02	Korangy
25.	I.K.	5/14/02	Korangy
26.	T.H.	5/14/02	Korangy
27.	A.K.	5/14/02	Korangy
28.	N.S.	5/14/02	Korangy
29.	C.J.	5/15/02	Shafique
30.	L.B.	5/15/02	Shafique

<u>No.</u>	<u>Patient Initials</u>	<u>Exam Date</u>	<u>Physician</u>
31.	D.W.	5/15/02	Shafique
32.	C.S.	5/15/02	Shafique
33.	M.M.	5/15/02	Shafique
34.	G.F.	5/16/02	Korangy
35.	S.R.	5/16/02	Korangy
36.	A.H.	5/16/02	Korangy
37.	C.B.	5/17/02	Korangy
38.	S.Q.	5/17/02	Korangy
39.	C.S.	5/17/02	Korangy
40.	S.G.	5/17/02	Korangy
41.	B.L.	5/17/02	Korangy
42.	G.B.	5/17/02	Korangy
43.	D.S.	5/17/02	Korangy
44.	F.S.	5/17/02	Korangy
45.	H.M.	5/20/02	Korangy
46.	C.H.	5/20/02	Korangy
47.	J.K.	5/20/02	Korangy
48.	D.R.	5/20/02	Korangy
49.	G.B.	5/20/02	Korangy
50.	A.D.	5/20/02	Korangy
51.	I.T.	5/21/02	Korangy
52.	D.M.	5/21/02	Korangy
53.	R.H.	5/21/02	
54.	R.E.	5/21/02	Korangy
55.	G.T.	5/21/02	Korangy
56.	I.W.	5/21/02	Korangy
57.	R.S.	5/21/02	Korangy
58.	R.A.	5/21/02	Korangy
59.	M.V.	5/22/02	Shafique
60.	A.M.	5/22/02	Shafique
61.	M.C.	5/22/02	Shafique
62.	S.W.	5/22/02	Shafique
63.	T.Z.	5/22/02	Shafique
64.	M.D.	5/22/02	Korangy
65.	A.K.	5/22/02	Korangy
66.	M.W.	5/22/02	Korangy
67.	N.M.	5/22/02	Shafique

<u>No.</u>	<u>Patient Initials</u>	<u>Exam Date</u>	<u>Physician</u>
68.	M.H.	5/23/02	Korangy
69.	H.S.	5/23/02	Korangy
70.	D.D.	5/23/02	Korangy
71.	M.F.	5/23/02	Korangy
72.	M.J.	5/23/02	Korangy
73.	E.M.	5/23/02	Korangy
74.	D.R.	5/23/02	Korangy
75.	L.R.	5/23/02	Korangy
76.	A.J.	5/24/02	Shafique
77.	M.B.	5/24/02	Korangy
78.	M.C.	5/24/02	Shafique
79.	D.P.	5/24/02	Shafique
80.	R.H.	5/28/02	Korangy
81.	E.W.	5/28/02	Korangy
82.	S.C.	5/28/02	Korangy
83.	C.R.	5/28/02	Korangy
84.	M.L.	5/28/02	Korangy
85.	C.D.	5/28/02	Korangy
86.	P.L.	5/29/02	Shafique
87.	M.G.	5/29/02	Korangy
88.	D.M.	5/29/02	Shafique
89.	W.M.	5/30/02	Korangy
90.	B.L.	5/30/02	Korangy
91.	A.P.	5/30/02	Korangy
92.	E.S.	5/30/02	Korangy
93.	G.D.	5/31/02	Shafique
94.	S.S.	5/31/02	Shafique
95.	P.P.	5/31/02	Shafique
96.	B.P.	5/31/02	Shafique
97.	J.A.	6/3/02	Korangy
98.	R.H.	6/3/02	Shafique
99.	A.H.	6/3/02	Shafique
100.	B.H.	6/3/02	Shafique
101.	L.G.	6/4/02	Korangy
102.	B.J.	6/4/02	Korangy
103.	B.E.	6/4/02	Korangy
104.	E.B.	6/4/02	Korangy

<u>No.</u>	<u>Patient Initials</u>	<u>Exam Date</u>	<u>Physician</u>
105.	M.A.	6/5/02	Shafique
106.	E.M.	6/5/02	Korangy
107.	M.B.	6/5/02	Shafique
108.	B.D.	6/6/02	Korangy
109.	R.B.	6/6/02	Korangy
110.	K.H.	6/6/02	Korangy
111.	M.S.	6/6/02	Korangy
112.	M.B.	6/6/02	Korangy
113.	C.D.	6/7/02	Shafique
114.	J.S.	6/7/02	Shafique
115.	M.S.	6/7/02	Shafique
116.	E.R.	6/7/02	Shafique
117.	S.F.	6/7/02	Shafique
118.	V.N.	6/7/02	Shafique
119.	E.B.	6/10/02	Hage
120.	J.O.	6/10/02	Hage
121.	B.H.	6/11/02	Korangy
122.	C.O.	6/11/02	Korangy
123.	K.Z.	6/11/02	Korangy
124.	E.M.	6/13/02	Korangy
125.	L.L.	6/13/02	
126.	D.R.	6/13/02	Korangy
127.	C.M.	6/13/02	Korangy
128.	P.D.	6/13/02	Korangy
129.	M.L.	6/13/02	Korangy
130.	I.L.	6/17/02	Hage
131.	D.S.	6/17/02	Hage
132.	M.S.	6/17/02	Hage
133.	M.Y.	6/17/02	Hage
134.	C.W.	6/19/02	Shafique
135.	K.M.	6/19/02	Shafique
136.	J.P.	6/19/02	Shafique
137.	P.P.	6/19/02	Shafique
138.	B.A.	6/20/02	Korangy
139.	P.Y.	6/20/02	Korangy
140.	W.F.	6/20/02	Korangy
141.	A.H.	6/20/02	

<u>No.</u>	<u>Patient Initials</u>	<u>Exam Date</u>	<u>Physician</u>
142.	K.M.	6/20/02	Korangy
143.	L.G.	6/21/02	Korangy
144.	M.M.	6/24/02	Korangy
145.	E.A.	6/24/02	Korangy
146.	J.H.	6/24/02	Korangy
147.	H.A.	6/24/02	Korangy
148.	A.W.	6/24/02	Korangy
149.	P.K.	6/24/02	Korangy
150.	H.F.	6/24/02	Korangy
151.	E.H.	6/24/02	Korangy
152.	C.H.	6/24/02	Korangy
153.	E.V.	6/25/02	Korangy
154.	E.N.	6/25/02	Korangy
155.	M.R.	6/25/02	Korangy
156.	I.R.	6/25/02	Korangy
157.	V.L.	6/25/02	Korangy
158.	D.K.	6/25/02	Korangy
159.	R.D.	6/25/02	Korangy
160.	S.P.	6/25/02	Korangy
161.	F.M.	6/26/02	Korangy
162.	P.H.	6/26/02	
163.	D.A.	6/26/02	Shafique
164.	L.W.	6/26/02	Shafique
165.	M.G.	6/26/02	Shafique
166.	H.S.	7/5/02	Shafique
167.	V.B.	7/5/02	Shafique
168.	G.P.	7/5/02	Shafique
169.	L.J.	7/17/02	Shafique
170.	D.W.	7/17/02	Shafique
171.	L.W.	7/17/02	Shafique
172.	P.P.	7/17/02	Shafique
173.	D.F.	7/17/02	Korangy
174.	S.B.	7/17/02	Korangy
175.	O.J.	7/17/02	Korangy
176.	L.B.	7/17/02	Korangy
177.	B.H.	7/17/02	Korangy
178.	A.L.	7/20/02	Shafique

<u>No.</u>	<u>Patient Initials</u>	<u>Exam Date</u>	<u>Physician</u>
179.	D.M.	7/20/02	Shafique
180.	C.R.	7/20/02	Shafique
181.	C.H.	7/20/02	Shafique
182.	G.P.	7/24/02	Shafique
183.	L.M.	7/24/02	Korangy
184.	G.P.	7/24/02	Shafique
185.	J.M.	7/24/02	Shafique
186.	G.P.	7/24/02	Shafique
187.	J.S.	7/24/02	Shafique
188.	H.D.	7/24/02	Korangy
189.	A.B.	7/24/02	Korangy
190.	V.B.	7/24/02	Korangy
191.	H.W.	7/24/02	Shafique
<u>192.</u>	<u>J.S.</u>	7/24/02	Shafique

I declare under penalty of perjury that the foregoing is true and correct.

Executed on April 2, 2004.


Michael P. Divine