

Pharmacy Jurisprudence, L.L.C.



For pharmacists in states with a pharmacy law continuing education (CE) requirement*, we offer our annual CE booklet free from commercial support.

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2 **Consequences of Non-Compliance with Federal Drug Laws**

Accreditations (Pharmacy): This continuing pharmacy education activity has been approved by the Ohio State Board of Pharmacy for Ohio Board-approved jurisprudence and accredited by ACPE for law-related continuing education for pharmacists and technicians.

Credit(s): 1.0 contact hours (0.1 C.E.U.)

Release Date: September 3, 2010

Expiration Date: August 9, 2012

Cost: \$15.00



Select CE® is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

* Except for states of ID, NV, and OR, which each have special state board requirements. Programs in this booklet are acceptable in states of AZ, CT, MA, NJ, OH, and UT, and all other states which recognize ACPE accreditation.

Program Title: Consequences of Non-Compliance with Federal Drug Laws
Target Audience: All Pharmacists, Nurses and Pharmacy Technicians
Release Date: September 3, 2010
Expiration Date: August 9, 2012
Ohio State Board of Pharmacy Program No.: 036-350-10-002-H03
ACPE Program No.: 487-000-10-002-H03-P knowledge-based activity
or 487-000-10-002-H03-T knowledge-based activity

Accreditations: This continuing education activity is approved by the Ohio State Board of Pharmacy for 1.0 contact hours, or 0.10 C.E.U.'s, of continuing pharmacy education in Board-approved jurisprudence. This program is also accredited by ACPE for pharmacists and pharmacy technicians under our trade name Select CE®.



Select CE® is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Nursing Accreditation and Non-endorsement Statement and Goal Statement:

This continuing nursing education activity is good for 1.0 contact hour of continuing nursing education.

This continuing nursing education activity was approved by the Ohio Nurses Association (OBN-001-91), an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation.

Approval valid through August 9, 2012. Assigned ONA #14,769-I.

Approved provider status does not imply endorsement by the provider, ANCC, OBN or ONA of any commercial products displayed in conjunction with an activity.

The goal of this activity is to improve understanding of federal drug laws.

Media: Enduring print material and **interactive test-taking at www.selectce.org.**

Fee Information: \$15.00

Estimated Time to Complete the Activity: 60 minutes

Procedures: To receive a Statement of Credit, read this program, complete the post-test questions and evaluation on the Answer Sheet, and either:

i) mail the Answer Sheet (page 14) and the program fee of \$15.00 to us. You will receive a Statement of Credit mailed to you within 2 weeks. Checks or money orders are encouraged. Mail to: Pharmacy Jurisprudence, P.O. Box 21186, Columbus, Ohio 43221-0186. Refunds are not provided.

or

ii) use our online test-taking website www.selectce.org. Follow the instructions on the website, using any major credit card to pay the \$15 program fee. Upon passing the test, you will receive immediate confirmation via email, and your official Statement of Credit will be sent via U.S. mail within 5 days but in most cases within 2 days. Refunds are not provided, unless you mistakenly make too many online payments or some such other online snafu.

A minimum score of 75% is required to earn a Statement of Credit.

Faculty: Patricia A. Nussle, R.Ph., J.D., is the founder of Pharmacy Jurisprudence and Select CE. She is also a healthcare attorney who has written and published continuing education programs in pharmacy law and nursing law for over 200,000 healthcare professionals since 2001.

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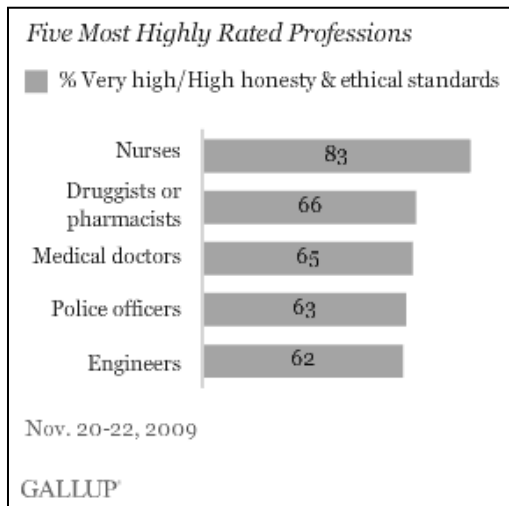
Objective: At the conclusion of this program, pharmacists and nurses should be able to describe at least 2 consequences of failing to comply with federal drug laws.

Objective: At the conclusion of this program, pharmacy technicians should be able to describe at least 2 consequences of failing to comply with federal drug laws.

Important Note: Colleagues, this is a continuing education program. It is not legal advice. Do not rely on this CPE program as legal authority. If you do have a legal problem or question, please consult an attorney experienced in pharmacy law matters to discuss your specific situation.

Thank you! We truly enjoy serving you.

Nurses, pharmacists, and medical doctors enjoy the top three spots in a recent Gallup poll survey of honest professionals.¹



For pharmacists, the high trust level is perhaps due in part to the steadily increasing educational requirements to become a pharmacist²:

<u>Educational Requirements for U.S. Pharmacists</u>	
1900's	– apprenticeship
1950's	– 4 year B.S. degree
1960's	– 5 year B.S. degree
1970's	– optional 2-year post-B.S. Doctor of Pharmacy degree
2000	– 6-year Doctor of Pharmacy degree

But sometimes pharmacists do things to damage their individual and collective reputations. And when it happens, we often read about it in the newspapers because pharmacists are such a highly trusted, highly educated profession.

We present to you recent stories of pharmacists, technicians and others who handle drugs who have “done wrong” and are living the consequences. These stories are taken from publicly available news sources, and we have no intent to embarrass or harm the people in the stories. But we believe we can and should learn from others. With that in mind, read on.

¹ <http://www.gallup.com/poll/124625/Honesty-Ethics-Poll-Finds-Congress-Image-Tarnished.aspx>

² <http://www.scribd.com/doc/12459523/Pharmacy-An-overview-of-one-of-the-worlds-most-trusted-professions>

Pharmacy Owner Sentenced for Expensive HIV/AIDS Prescriptions Never Dispensed³

On April 6, 2010 the owner of a Newark pharmacy was sentenced in connection with an investigation into pharmacy owners and employees who bought completed prescription forms for HIV/AIDS drugs from indigent patients so Medicaid could be billed for drugs that were never actually dispensed.

According to New Jersey Acting Insurance Fraud Prosecutor Riza Dagli, Nwala Gabriel, 49, of Piscataway, was sentenced to three years of probation by Superior Court Judge Michael A. Petrolle. Judge Petrolle also ordered Gabriel to pay \$178,272 in fines and restitution and to serve 150 hours of community service. Gabriel will be excluded from the Medicaid program for three years. He must surrender his license to practice pharmacy for a minimum period of three years or until he successfully completes all terms of his criminal sentence.

The sentence was based on Gabriel's guilty plea to Medicaid fraud. The charge was contained in a state grand jury indictment obtained by the Office of the Insurance Fraud Prosecutor's Medicaid Fraud Control Unit on Oct. 26, 2009.

In pleading guilty on Feb. 23, Gabriel, the owner of Harrison Pharmacy on Martin Luther King Boulevard in Newark, admitted that he fraudulently billed Medicaid for prescription drugs that were never dispensed to the Medicaid beneficiaries.

Gabriel was charged as a result of Operation PharmScam, an ongoing investigation targeting Medicaid fraud that began in 2008 and has been conducted by OIFP's Medicaid Fraud Control Unit, the Jersey City Police Department and the U.S. Food and Drug Administration's Office of Criminal Investigations.

On Oct. 26, 2009, a total of 11 defendants, including Gabriel, were indicted as a result of the investigation into pharmacies that were buying prescriptions from patients and billing the Medicaid program for medicines that were never dispensed.

On Jan. 19, two technicians at Pharmacy of America who were indicted, Jannah Rasheedah Amatul Muid and Alicia Stephens, pleaded guilty to Medicaid fraud. On March 8, Muid and Stephens were sentenced to three years probation, ordered to pay a \$1,000 civil fine and were barred from participating in the Medicaid Program for a period of five years.

³ <http://www.nj.gov/oag/newsreleases10/pr20100406a.html>

Muid was ordered to perform 150 hours of community service, while Stephens was ordered to perform 100 hours of community service. On the same day, Shivonne Forde, another Pharmacy of America technician, pleaded guilty to third-degree possession with intent to distribute prescription legend drugs.

Connecticut Pharmacist Sentenced for Medicaid Fraud⁴

The registered pharmacist who operated a now-bankrupt Manchester pharmacy was sentenced today for cheating the government by charging bogus fees to fill prescriptions for Medicaid recipients.

Roy D. Katz, age 52, pleaded guilty in Hartford Superior Court to two counts of Fourth Degree Vendor Fraud, a class A misdemeanor. Pursuant to the plea agreement, the Honorable Bradford J. Ward sentenced Mr. Katz to a total effective term of two years imprisonment, execution suspended, and three years probation.

Mr. Katz is paying \$1.115 million in restitution to the government as a result of a separate settlement with the Office of the Attorney General and the United States Attorney for the District of Connecticut.

Mr. Katz is a registered pharmacist who was president and principal owner of the now-bankrupt R.G. Pharmacy, Inc., which did business as The Medicine Shoppe in Manchester. A former president of the Connecticut Pharmaceutical Association, he was excluded as a Medicaid provider for seven years as a result of an administrative proceeding that concluded in December 2009.

Question 1:

If you bill Medicaid for medications that were never dispensed, you can expect:

- a. to make restitution to the Medicaid program;
- b. fines;
- c. both of the above.

Question 2:

If you bill Medicaid for medications that were never dispensed, you can expect:

- a. to be excluded from filling any Medicaid prescriptions for a period of time;
- b. a criminal conviction;
- c. both of the above.

Question 3:

Who can be found guilty of a felony for billing Medicaid for medications that were never dispensed?

- a. pharmacists;
- b. technicians;
- c. both can be found guilty.

⁴ <http://www.ct.gov/csao/cwp/view.asp?a=1801&q=457868>

Mr. Katz was arrested in November 2008 as a result of an extensive investigation conducted by Inspectors in the Medicaid Fraud Control Unit in the Office of the Chief State's Attorney.

The investigation disclosed that pharmacists and pharmacy technicians employed by and acting at Mr. Katz's direction altered prescriptions for 30-, 60- or 90- day supplies of various medications for Medicaid recipients, by dividing those prescriptions into 7-day units of medication.

Medicaid pays pharmacies a dispensing fee for each prescription filled. By unlawfully dividing a single prescription into multiple units, Mr. Katz's pharmacy was able to bill for multiple fees and not just the single fee to which it was entitled.

An examination of the prescription records of six Medicaid recipients for various periods between October 2002 and December 2006 found overcharges for dispensing fees totaling more than \$4,200 for those patients alone. Mr. Katz's fraudulent scheme is estimated to have cost the government more than \$3.2 million in bogus fees.

Question 4:

Altering prescriptions that are paid for by the federal government in order to bill for multiple dispensing fees can result in:

- a. a criminal conviction;
- b. restitution to the federal government;
- c. both of the above.

Former NJ and Connecticut Pharmacist Sentenced to 14 Months in Federal Prison for Health Care Fraud⁵

On April 30, 2010, Joby George, 35, of Cliffwood, New Jersey, was sentenced by United States District Judge Mark R. Kravitz to 14 months of imprisonment, followed by two years of supervised release. On July 10, 2009, the pharmacist pleaded guilty to one count of health care fraud.

According to court documents and statements made in court, between June 2006 and September 2008, Mr. George was a pharmacist, licensed in Connecticut, New Jersey and New York, and a part owner of Byram Pharmacy in Greenwich, Connecticut. During this time period, Mr. George knowingly and willfully submitted, or caused to be submitted, fraudulent claims for payment to the Medicaid and Medicare programs. Specifically, he submitted various claims to Medicaid for certain prescription drugs that were not, in fact, dispensed. He also submitted various claims to Medicaid for certain brand name drugs when, in fact, he had dispensed less expensive generic drugs.

⁵ <http://newhaven.fbi.gov/dojpressrel/2009/nh071009.htm>

Mr. George had previously entered into a civil settlement agreement with the Government in which he has paid \$344,805 to resolve allegations that he violated the False Claims Act. The Government has alleged in the settlement agreement that Mr. George improperly submitted claims to Medicare for certain prescription narcotics that he dispensed to an individual while accepting cash payments from the same individual for additional quantities of those drugs.

Mr. George agreed to surrender all of his pharmacist licenses.

Doctor Sentenced to 1 Year in Prison for \$1 Million Fraud⁶

While this story does not involve a pharmacist or pharmacy technician, it does contain an important teaching point about the costs of the government's investigation.

Question 5:

The 35-year-old pharmacist in New Jersey lost his license and is going to jail for 14 months because he:

- a. dispensed less expensive generic drugs while billing the government for brand name drugs;
- b. submitted claims for medications that he never dispensed;
- c. submitted claims to the government for narcotics for which he accepted cash from the patient;
- d. all of the above are true.

Question 6:

The government can pass the costs of its healthcare fraud investigation on to the guilty healthcare professionals:

- a. yes;
- b. no;
- c. only if the guilty agrees to it.

On May 5, 2010, before a packed federal courtroom, a doctor who admitted to submitting more than \$1 million in false insurance claims to Medicare and private insurers over a five-year period was sentenced to a year behind bars.

Dr. John Kristofic, 62, has already paid \$3.3 million to the government for restitution and for costs of the investigation. He shut down his practice on May 1 and will almost certainly lose his medical license.

Prosecutors said Dr. Kristofic, who has been accused of healthcare fraud before, submitted false claims for services he never rendered between 2003 and 2008.

⁶ <http://pittsburghpost-gazette.com/pg/10125/1055746-100.stm>

Chief U.S. District Judge Donetta Ambrose said that the doctor, an internal medicine specialist, was a "puzzle" to her. On one hand, she received 60 letters of support from people extolling his virtues in providing care to addicts and the homeless in Pittsburgh and to the sick and destitute in Haiti.

But she also said he had committed serious healthcare fraud, a felony offense in which "everyone suffers" at a time when healthcare costs are a national issue.

"It's cheating," she said. "It's stealing."

What's more, she and the government noted, Dr. Kristofic has been accused of similar conduct in the past, which led to a federal conviction in 1991. In the 1980s, he was accused in a civil case brought under the federal Racketeer Influenced and Corrupt Organizations Act of submitting false bills at his practice and using the proceeds to invest in commercial real estate.

Although his days of practicing are probably over, Judge Ambrose said, she did give him a substantial break. She could have sent Dr. Kristofic to prison for three years. But she granted him leniency because of his good works in the community.

Ohio Pharmacist Convicted of \$1 Million Drug Fraud⁷

A rural Ohio pharmacist has been sentenced to 36 months in federal prison for health-care fraud for submitting more than \$1 million in "dummy bills" to Medicaid.

Pharmacist Brian L. Martin had told investigators that the billings at his Blanchester pharmacy in Clinton County were a mistake. He has made restitution of more than \$1 million.

"Dummy bills" are requests for payment submitted to Medicaid to determine whether the patient and drug are eligible for coverage and how much the patient would have to pay. The pharmacist cancels the order if the prescription is not filled; if it is, the request automatically goes through.

Martin's defense attorneys from the Dinsmore & Shohl firm in Cincinnati argued in court that many of the dummy orders were canceled.

However, Judge Ed Sargus ruled that Martin, 32, was guilty of all 37 counts of filing false health-care statements and health-care fraud.

⁷http://www.dispatch.com/live/content/local_news/stories/2008/09/23/pharmacist_fraud.ART0_ART_09-23-08_B3_M1BDERU.html

Some of the drugs for which Martin obtained payments were among the most expensive on the market, the judge noted: Zyprexa®, an anti-psychotic drug, costs up to \$1,200 for 60 tablets; Zofran®, an anti-nausea drug, can cost \$1,000 for 30 tablets; and Imitrex®, which treats migraine headaches, can cost \$200 for nine tablets.

Sargus said he didn't believe that Martin used the "dummy bills" simply to see whether patients were Medicaid-eligible. Many times, customers had a different prescription approved by Medicaid earlier on the same day, the judge noted.

Prosecutors alleged that Martin conducted the fraud over 18 months at the pharmacy he co-owned, beginning soon after it opened in 2004. In that period, the fraud netted the pharmacy an additional \$1 million in profits.

Martin didn't notify Medicaid of the billing error until after pharmacy co-owner Kris Gundler learned of the federal investigation in the summer of 2005. Gundler, who is also a pharmacist, was not indicted in the scheme and was responsible for only a fraction of the bills that should have been canceled.

Four Arrested in Synagis® (palivizumab) Investigation⁸

On January 28, 2010, four individuals were arrested in connection with an ongoing investigation into suspected health care fraud at Three Rivers Infusion and Pharmacy Specialists (Three Rivers) in Coshocton, Ohio.

A federal indictment charges 55-year-old Barbara Elise Miller of Coshocton, owner of Three Rivers, with two counts of witness tampering, two counts of

Question 7:

In Ohio, a pharmacist who is found guilty of 37 counts of filing false healthcare statements and healthcare fraud could:

- a. serve 36 months in jail;
- b. make restitution of over \$ 1 million;
- c. both.

Question 8:

Co-owners of a pharmacy in which healthcare fraud occur are always jointly liable for the wrongful acts that occur in the pharmacy:

- a. True;
- b. False.

⁸ <http://www.ohioattorneygeneral.gov/Briefing-Room/News-Releases/January-2010/Four-Arrested-in-Health-Care-Fraud-Investigation>

obstruction of an official proceeding and one count of concealment of records. Miller's husband, 50-year-old Dana C. Campbell, a non-pharmacist employed by Three Rivers, is charged with one count of concealment of records.

Also arrested in 2010 were 55-year-old Douglas A. Bolden and 39-year-old James O. Ireland, both of Zanesville. Bolden and Ireland worked for Three Rivers. Each is charged with one count of obstruction of an official proceeding.

“This case began with concerns about suspected overbilling of medical insurance companies for services and for drugs,” said Attorney General Richard Cordray. “By working in partnership with federal authorities, our investigators are weeding out and attacking health care fraud wherever we find it.”

In August 2008, investigators searched Three Rivers and seized various files, including files of patients who received Synagis® (palivizumab), a drug used to treat high-risk infants in the prevention of Respiratory Syncytial Virus (RSV).

Question 9:

Patient files in the pharmacy are:

- a. the property of the pharmacy, and can never be surrendered to law enforcement;
- b. contain personal health information, and can never be surrendered to law enforcement;
- c. can be surrendered to law enforcement, upon presentation of a proper subpoena.

Question 10:

Suspected cases of overbilling of medical insurance companies for services and drugs can spark a state investigation:

- a. True;
- b. False.

In December 2008, the government served Three Rivers with a subpoena to produce 118 patient files, but Three Rivers provided the government with only 21 files. In December 2009, government agents found many of the subpoenaed patient files concealed in Miller's and Campbell's home in Coshocton.

The indictment charges that Bolden and Ireland accused Miller of using Bolden's name as the pharmacist who was dispensing the drug Synagis when Bolden had not done so. The government alleges that Miller provided “severance” payments to both Bolden and Ireland in return for their silence about Miller's activities.

If convicted, the defendants' sentences will be determined by the court after review of factors unique to this case, including any prior

criminal records, the defendants' roles in the offense and the characteristics of the violation. In all cases the sentence will not exceed the statutory maximum and in most cases it will be less than the maximum.

The Ohio Attorney General reminds us that an indictment is only a charge and is not evidence of guilt. Each defendant is entitled to a fair trial in which it will be the government's burden to prove guilt beyond a reasonable doubt.

Ex-Pharmacist Convicted of Taking Payments⁹

A former Pennsylvania pharmacist was fined \$3,000 and sentenced to 18 months' probation after being convicted of taking payments from drug companies and pocketing money for supervising interns on state time.

Steven Fiorello, 61, was director of pharmacy for Pennsylvania's Office of Mental Health, Substance and Abuse Services and secretary of a committee that approved Medicaid-paid drugs in state hospitals, prisons and juvenile centers from 1998 to 2003 when he accepted money from drug companies for consulting work, trips and honorariums, state prosecutors said.

A criminal complaint said Fiorello accepted perks from Pfizer and Janssen, two companies that promoted the use of psychiatric drugs in state hospitals.

Also, authorities charged that Fiorello used his state position to pocket \$2,400 from Duquesne University for supervising pharmacy interns at state hospitals between 2000 and 2003, prosecutors said.

Fiorello was convicted of two felony conflict-of-interest charges and two misdemeanors last month, after a nonjury trial before Dauphin County Common Pleas Judge Richard Lewis.

Lewis also sentenced Fiorello to 250 hours of community service. Fiorello paid more than \$27,000 in civil fines after the state Ethics Commission cited him for ethics violations in connection with the same allegations in 2005.

Novartis Vaccines & Diagnostics to Pay More Than \$72 Million to Resolve False Claims Act Allegations Concerning TOBI¹⁰

Novartis Vaccines & Diagnostics Inc. and Novartis Pharmaceuticals Corporation will pay \$72.5 million to resolve civil False Claims Act allegations arising from the marketing of the cystic fibrosis drug TOBI®. The settlement

⁹ http://www.pittsburghlive.com/x/pittsburghtrib/news/pittsburgh/s_608230.html

¹⁰ <http://www.justice.gov/opa/pr/2010/May/10-civ-522.html>

resolves allegations that, between Jan. 1, 2001 and July 31, 2006, Novartis and its predecessor, Chiron Corporation, caused false claims to be submitted to federal health care programs for certain off-label uses of the drug.

The Food and Drug Administration (FDA) approved TOBI, an inhaled antibiotic, for the treatment of certain cystic fibrosis patients. The United States alleges that Chiron, and then Novartis, marketed TOBI for unapproved uses, such as diseases other than cystic fibrosis, and for cystic fibrosis patients who did not meet the parameters of the FDA-approved indication and for which TOBI was not a medically accepted use. The government alleges that this conduct caused the submission of false claims to federal health care programs.

"Pharmaceutical companies must not promote their drugs for uses that have not been proven to be safe and effective," said Tony West, Assistant Attorney General for the Department of Justice. "We are committed to pursuing False Claims Act violations and recovering taxpayer dollars lost to off-label marketing."

"This office is committed to safeguarding the federal health care programs against false claims caused by off-label marketing and other types of illegal conduct," said the U.S. Attorney for the Northern District of California.

Under the agreement, the proceeds from the settlement will be divided between the federal government and various states, with the United States receiving \$43.5 million and the states receiving \$29 million.

This settlement resolves a lawsuit brought by three former Chiron employees – Robert Lalley, Courtney Davis and William Manos – under the *qui tam* or whistleblower provisions of the False Claims Act, which permit private individuals known as relators to bring a lawsuit on behalf of the United States and to share in any recovery. The relators will receive \$7.825 million of the federal share of the settlement.

Question 11:

Not disclosing that you pocketed payments for supervising pharmacy interns at state hospitals can result in:

- a. conflict of interest charges;
- b. misdemeanor charges;
- c. both.

Question 12:

Off-label marketing:

- a. means promoting a drug for uses that have not been proven to be safe and effective;
- b. can result in lost taxpayer dollars;
- c. both

Return this ANSWER SHEET with the \$15.00 Program Fee payable to:

*Pharmacy Jurisprudence, LLC
P.O. Box 21186
Columbus, Ohio 43221-0186*

NAME:
ADDRESS:
CITY, STATE and ZIP:
TELEPHONE:
EMAIL:

ANSWERS: Consequences of Non-Compliance with Federal Drug Laws

Expiration Date: August 9, 2012

Circle the answer for each question (questions are imbedded in the program).

- | | | | | | | | | |
|----|---|---|---|-----|-----|---|---|---|
| 1. | a | b | c | 7. | a | b | c | |
| 2. | a | b | c | 8. | a | b | | |
| 3. | a | b | c | 9. | a | b | c | |
| 4. | a | b | c | 10. | a | b | | |
| 5. | a | b | c | d | 11. | a | b | c |
| 6. | a | b | c | 12. | a | b | c | |

13. For Pharmacists: After completing this program, I am able to recognize at least 2 consequences of failing to comply with federal drug laws: Yes No

13. For Technicians: After completing this program, I am able to recognize at least 2 consequences of failing to comply with federal drug laws: Yes No

13. For Nurses: After completing this program, I am able to recognize at least 2 consequences of failing to comply with federal drug laws: Yes No

14. This program was an effective way for me to learn: Yes No

15. I liked the program's format: Yes No

16. This program fostered my mental participation: Yes No

17. This was a "user-friendly" way for me to learn: Yes No

18. I could sense some commercialism in this program: Yes No

If yes, please describe: _____

19. The faculty quality was: Great OK Needs to Improve

20. The learning material quality was: Great OK Needs to Improve

21. How long did it take to complete this program? _____

22. What other topics would you like to see? _____

23. Comments welcome! _____