Sections in This Document

1. Introduction

Science plays an increasingly significant role in many types of legal proceedings. The regulatory analyst is aware that their analytical methods and findings may be challenged in a court of law. The Food, Drug, and Cosmetic Act deals with government's attempts to protect public health and individual welfare by regulating the development and marketing of essential commodities. Analysts, engineers, inspectors, and investigators all play a part in the regulatory process, working in concert to uncover and document violations of the law. These violations of the law may stimulate a variety of responses, such as the warning letters, injunctions, seizure, civil and criminal charges and voluntary actions by the food industry and other responsible parties.

If subpoenaed to appear as a witness in a court case, the analyst should try to gain as much information as possible about the trial process and what to expect. The potential witness should know the basics of the work performed,

be aware of proper deportment in the courtroom, and understand the elements of the scientific defense. A prospective witness, who is particularly nervous about testifying in court, should "sit in" on a trial where scientific testimony is being given. Most court sessions are open to the public. Local court cases regarding illicit drug use, possession, or sale, which sometimes involve scientific testimony, occur almost daily in most moderately sized communities. Call the local district attorney's office or courthouse to find out when such cases will be tried. This document includes an attachment, " How to be a Good Witness," which offers helpful suggestions for potential witnesses.

Analysts who expect to testify should contact others in the field or headquarters who have experience in testifying in agency-related matters; analysts, compliance officers, General Counsel, and others can provide valuable information and insight. Staging a mock trial with laboratory personnel, investigations, and/or compliance personnel can be an excellent preparation exercise. Take advantage of oral reviews to practice answering questions related to analytical work if conducted at the district office or laboratory.

This chapter provides general guidelines and suggestions for the potential witness. Additional sources on science-based testimony are given in Section 5 General References.

2. The Basics

The basics include those factors that are most familiar to Food and Drug Administration (FDA) analysts such as the chain of custody of samples, the analysis performed on the product including the results, and quality control procedures associated with the product or sample analysis. Since an FDA analyst represents the Agency and its enforcement efforts in court, every effort will be made to provide the proper training, guidance, and preparation prior to court room testimony.

2.1. Pre-Trial Conference

A. The witness will have the opportunity to discuss testimony with the government attorney at a pre-trial conference. This is the time to ask questions and to ensure that the government attorney fully understands the analyst's testimony. Any unresolved concerns and issues, such as problems with sample integrity, should be settled by this stage. The witness's answers at trial should not be changed without the prior knowledge of government counsel.

B. The pre-trial conference is also the time to ask any logistical questions. Witnesses should ask the attorney whether they are expected to go directly to the courtroom or to another room while waiting to give

testimony. Witnesses also need to know where they should go after testifying; should they remain in the courtroom or in the building, or are they free to leave?

C. Whether testifying as a fact witness or an expert witness (see Section 4.1), analysts will be asked about their qualifications and professional history. Knowledge of a witness's schooling, experience, and professional achievements, including specialty certifications, training, and areas of expertise, may have a positive effect on the jury by lending credibility to responses. However, recounting every detail of one's professional life may bore the jury. The witness, therefore, should discuss with the attorney which accomplishments should be disclosed.

2.2. Chain of Custody

One of the first areas of testimony will involve the chain of custody. "Is the sample that was analyzed in the laboratory the same sample that the investigator picked up at the firm?" "Was the sample tampered with, or contaminated, at any point?" The analyst can testify only to that about which he or she has actual knowledge. Most likely the first contact with the sample occurred when it was picked up from the sample custodian. This may have been followed by completion of the sample accountability record, breaking the official seal(s), performing the analysis, resealing the sample, and returning it to the sample custodian. See ORA Laboratory Manual, Volume III, Section 2 (Chain of Custody – Sample Handling) for a complete discussion of sample accountability. The analyst may be asked about the conditions under which the sample was stored while in the analyst's care. "Who, besides yourself, had access to the sample?" Remember the legal position of "presumption of regularity"; i.e. this is the way the employee always does his/her work.

2.3. The Analysis

2.3.1. The Tests

A. It is very important for the analyst who is to give scientific testimony understand the basic principles of the tests performed and the instruments used. The analyst may have performed the same analysis for twenty years, but if clear, concise, and confident answers cannot be given to basic questions the impression is that poor work has been done for the past twenty years. The fact that an analyst runs a gas chromatograph every day does not mean that he or she understands the basic theory and principles of operating the instrument.

B. The analyst should avoid being coerced into detailed explanations of methods and equipment. Stating that the method or equipment is widely accepted for use by Federal and State laboratories can help to keep

detailed descriptions to a minimum. If directed by the judge or counsel to provide details or additional explanation, the simplest, clearest answer should be given; for example, rather than providing an exhaustive account of the Association of Official Analytical Chemists (AOAC) collaborative process, stating that AOAC INTERNATIONAL methods are recognized as the official methods of analysis would suffice.

C. The jury is the audience. The use of jargon and scientific terms unfamiliar to jurors should be avoided. A jury that does not understand the terms used by a witness will not understand the message given in the testimony. The scientist is trained by experts in his or her chosen field, by reading professional journals, and through conversations with colleagues. Repeating lengthy conversations or communications, although meaningful to associates, may be difficult or impossible for the layman or non-scientist to understand. The scientific witness presents analytical findings so that all members of the jury, the judge, and the attorneys can easily grasp the significance of the testing and results. Technical expressions are clearly and carefully explained. A jury may know very little, if anything, about the laws of science, the accumulation of evidence, precautions taken to avoid error, and statistical interpretations.

D. The analyst should practice giving explanations of methodologies and techniques. The analyst may be very familiar with the procedures used but may have less experience explaining the procedures to those unfamiliar with the scientific principles involved. When possible, the analyst should describe the principles in understandable, everyday terms without being condescending. For example, capillary action by which a solvent migrates up a thin layer chromatography plate can be compared to the mechanism by which water travels up a dry paper towel.

2.3.2. The Method

The analyst is to understand the method used. Why was it chosen? How or why does it work? Responses such as, "Because my supervisor told me to," or "We always use that method," are not acceptable responses. The FDA policy has always been that, when in existence, official methods are used for sample analyses that are the basis for regulatory action. See ORA Laboratory Manual, Volume II, Chapter 5.4.5 (Methods, Method Verification and Validation) for an explanation of Official Compendia and Analytical Manuals, respectively. The analyst may need to explain the meaning of a method's official status. Remember, use of official methodology does not relieve the analyst of the

responsibility of proving method performance through quality controls, positive and negative controls, and recovery and reproducibility studies. Be prepared to explain why recoveries or certified reference materials were run; how they were run; and what they proved. Be prepared for questions concerning shortcomings of the methodology used and possible alternative methods that others may consider more reliable.

2.3.3. The Worksheet

A. One of the most important things the FDA analyst can do to ensure smooth testimony in court is to establish good analytical habits. Many analysts may hear senior coworkers state that they have been with the government for "X" number of years and have never been called to testify. Although this may be true, it is important to maintain credible, high quality science and documentation in the laboratory. Experience is not a substitute for good quality control. Before a case can proceed to trial, the veracity of the analytical findings is supported through the use of Quality Assurance/Quality Control (QA/QC) procedures. The analyst's worksheets will be subjected to many layers of review before they become introduced in a court of law. The analysis and documentation must be complete and meet agency standards of quality to survive the scientific and legal scrutiny in the courtroom.

B. Proper documentation will be the basis for much of the analyst's testimony. By the time a case gets to court many months, if not years, may have passed since the analysis was performed. It is very unlikely that the analyst would recall details about the case or details of the analysis.

2.3.4. Quality Controls

A. Analysts must have knowledge of their local laboratory quality system. For example, if part of the analysis involved recording a critical temperature, the analyst is to document that the thermometer was checked for accuracy on a regular basis and the thermometer met the specifications before it was used in the analysis. This quality control applies to other instruments and equipment as well, and the local quality system should address the conditions for operation and specifications.

B. If the method used was not studied collaboratively or validated for the matrix in question, the analyst should be prepared to explain what types of validation were performed. Validation factors such as the use of method blanks, system suitability, certified reference material, and recoveries may be incorporated into the method. (See ORA Laboratory

Manual, Volume II, ORA-LAB.5.4.5 Methods, Method Verification and Validation).

3. Giving Testimony

A. One of the best means of anticipating what questions the defense will ask is simply to see the case from the defense perspective. "What questions would I ask myself to invalidate this testimony?" The District should set up a mock trial involving fellow analysts, supervisors, and compliance officers. Hold an informal roundtable discussion or a more formal setup where peers can provide the inquisition the analyst may face on the witness stand. This can be one of the most helpful experiences before trial. Unanticipated questions may come to light and in some instances may provide the analyst with a better understanding of how he or she will react under pressure.

B. The principles enumerated in the Attachment “How to be a Good Witness” are the result of observations in court of some of the things that witnesses could have done to make their appearance on the stand and the presentation of their testimony more effective.

4. The Scientific Witness

An FDA analyst’s role in the courtroom is to serve as a scientific witness. The analyst needs to attest to what took place while examining a product in the laboratory. He or she provides an explanation of the underlying science and scientific testing procedures used to test the product. Most analysts serve as witnesses of fact.

4.1. Witness: Fact vs. Expert

A. Witnesses presenting scientific testimony fall into two categories: witnesses of fact and expert witnesses. Fact witnesses, even those who have scientific training, can testify only to matters of fact that they have witnessed. They cannot give opinions. The expert witness is one who, by special study, practice, and experience, has acquired special skill and knowledge in relation to some particular science, art, profession, or trade.

B. Qualifying as an expert involves an examination of the individual's academic credentials and the duties connected with his or her career, past and present, such as various professional achievements and the publication of original scientific papers. The possession of a bone fide degree from a State university, employment of some duration by a State or Federal agency in the scientific field covered by the testimony,

recognition by other institutions and organizations, and previous testimony in other cases helps to qualify a person as an expert witness.

C. The main reason for expert testimony is to interpret difficult-to-comprehend facts to the jury. The judge usually explains to the jury that the court will permit the expert to evaluate the evidence and explain its significance to the case being examined. Even though an expert witness is entitled to give opinions, usually more than a mere statement of opinion is usually needed for maximum impact. The expert witness should know or conclude that certain conditions or findings prove the statements he or she makes.

4.2. Scientific Defense

A. One of the burdens of proof in a case involving scientific testimony is that the science is sound and accurate. For example, in a case involving misbranding or adulteration, the prosecution demonstrates, beyond a reasonable doubt, that the product is actually misbranded. If the charge is subpotency of a drug, the science first shows that the drug in question is actually subpotent, if this is the basis of the allegation. This type of proof usually is provided by the analyst who analyzed the sample in question. The proof may be provided in the form of written results on the worksheet or verbal testimony of the analyst. In many cases the defense may stipulate to the report of the analyst. In other words, the defense is saying that they do not contest the report, nor do they question the integrity of the analysis performed. In such cases, the analyst may not be asked to testify.

B. In other instances, the entire basis of the defense may be that the results found are totally inaccurate. For example, the insect fragment in the soup was not actually an insect but an exotic vegetable; the drug analyzed was not subpotent because the chemist did not know what he or she was doing; the Salmonella found in the cheese was actually a result of cross contamination in the laboratory caused by a technique error made by the microbiologist. In these situations, the analyst may be asked to testify.

C. The basis of a scientific defense is to cast doubt on the conclusions drawn from the analysis. This type of defense can be difficult to perform because the defense attorneys may not know enough about the subject to ask the right questions. Even if they learn enough to ask the right questions or are knowledgeable about the science, the jury may not understand what is being said. In cases where the defense brings in expert scientific witnesses to contradict the testimony and the

conclusions of the prosecution's scientific witness, there is always the problem of whom the jury will believe.

D. Scientific defenses are generally a last resort when no other defense is feasible, or when the science is poor enough to warrant a court challenge. Nonetheless, an attorney who decides to use this defense will do his or her homework and at least gain an understanding of the principles behind the primary tests performed by the analyst. Without this knowledge the defense has no way of impeaching the expert witness.

5. General References

A. U.S. Food & Drug Administration, Office of Regulatory Affairs.(current edition). Investigations operations manual or the website address, http://www.fda.gov/ICECI/Inspections/IOM/default.htm

B. "Court Testimony" ST-1910 Federal Law Enforcement Training Center, Office of General Training, Legal Division 8-82

C. U.S. Food & Drug Administration, (current edition). Regulatory Procedures Manual, Chapter 6, Judicial Actions or the website address, http://inside.fda.gov:9003/PolicyProcedures/GuidanceRegulations/RPMMasterList/default.htm

D. ORA U Course FDA46 (Version 1.2), Courtroom Testimony.

E. 28 United States Code 1746.

6. Document History

Revision #	Status* (D, I, R)	Date	Author Name and Title	Approving Official Name and Title
1.2	R	02/06/12	LMEB	LMEB
1.3	R	01/29/13	LMEB	LMEB
02	R	08/13/2019	LMEB	LMEB

* - D: Draft, I: Initial, R: Revision

7. Change History

Revision #	Change
1.2	8.2.1 – changed "at" to "by" in third sentence of first paragraph; added "need to" to last sentence of second paragraph 8.2.2 – added last sentence 8.2.3.3 changed "is to" to "must" in last sentence of first paragraph 8.2.4 – deleted "general" from first sentence of first paragraph; deleted last sentence of last paragraph and added ORA LM reference 8.3 – changed "me" to "myself" in second sentence and revised third sentence 8.4.1 – deleted last sentence of first paragraph; revised second paragraph 8.5 – deleted outdated references and added reference Attachment – deleted Attachment I and II; added "How to be a Good Witness" 8.6 – added
1.3	Header – Division of Field Science changed to Office of Regulatory Science 8.5 – Division of Field Investigations and Office of Enforcement removed
02	The document was reformatted and few minor clarification changes were made.

8. Attachments

List of Attachments

Attachment A - How to be a Good Witness

Do...

Be alert. Beware when opposing counsel either attacks or strokes your ego. He or she may be trying to spur emotion to the detriment of the government case. Ignore this tactic. Be wary of forced, rapid questioning by opposing counsel. You have a right to have clear, understandable questions asked one at a time. Watch out for multiple questions phrased as one question. Ask for separate questions, if necessary. Be alert to opposing counsel re-phrasing your answer and asking if you agree. The change may sound innocuous, but it may soften what you said, sometimes to the detriment of the case.

Be objective. Do not tailor or slant your answers. You are here to testify the facts as you know them, without any bias. Be fair to the defendant.

Be brief. If a question can be answered in one word, do so and stop. Avoid volunteering information. Do not make unnecessary elaborations to your answer. If a question is so vague or ambiguous that it cannot be answered with a simple “yes” or “no,” answer it fully, but succinctly.

Be truthful. If you do not know the answer to a question, be truthful and say so. Do not guess at the answer. If a question requires a “yes” or “no” answer, but that would be misleading, explain that. Give the responsive one-word answer and then explain your answer.

Be direct. An evasive answer will indicate that you are trying to hide something. Do not give any ambiguous answers, and do not “beat around the bush.” If you must give an estimate for your answer, make it clear that you are giving an estimate.

Do not...

Do not accept re-wording unless it is exactly what you want to say. Often the defense may try to use your answers to questions asked during the deposition to change the meaning of what you are saying on the witness stand. Make sure you have thoroughly read your deposition transcription before trial, as the question asked during the trial may be different from, or out of context with what was asked during the deposition.

Do not take documents or other exhibits to the stand with you. They must be formally introduced, on the record. The Court allows you to use your notes to refresh your memory but, if used, they must have been made available to defense counsel for his or her review as part of the discovery process, may be marked as evidence, and retained as an exhibit. Only use your notes if the question involves a level of specificity that a normal person would not be expected to remember. Make certain that the government attorney presenting your testimony has reviewed all notes beforehand and agrees that they can be used.