

Case Study:

The Canons and interpretive guidelines are difficult to interpret and apply in the abstract. Short of actual experience, a more concrete way to portray ethical principles is through a plausible scenario. In the context of professional ethics, a scenario can illustrate the critical role technical considerations play in ethical issues and convey the ambiguity inherent in many of the situations a professional can face. In placing themselves in the roles of different characters, participants can attempt to interpret and apply ethical principles and guidelines as they come to terms with the dilemmas presented in the case. The scenario illustrates how the Canons can be applied to aid the professional in arriving at an ethical course of action.

The Scenario¹:

Product POHC, a new biodegradable and environmentally-safe plastic, is manufactured by the Better Living Chemical Company (BLC). POHC has been very much in demand and has increased BLC stock prices dramatically. During the first year of production, several women on the monomer line reported miscarriages. There has been talk among the employees about the possible health effects of POHC.

To ensure that the reproductive effects were not above expected incidence or related to the monomer, BLC requested the Industrial University Occupational Hygiene Department to design a study to address the issues. The proposed pilot study to determine exposure levels and administer a questionnaire to the workers was initially funded.

Last week, Industrial University submitted the written findings of the pilot study. The findings suggest that the reproductive effects may be related to exposure to the monomer. The Investigator wants to announce these results at the upcoming AIHCE in St. Louis. BLC invokes their contractual right to review findings prior to publication.

Cast of Characters:

¹ Adapted from Scenario Number Three presented at the 1995 AIHCE Ethics Forum. Used with permission of the AIHA Ethics Committee.

Dr. Impinger: Associate professor at Industrial University, Principal Investigator on the POHC project.

Dr. Dose: Head of the Department of Occupational Hygiene at Industrial University.

Patty: Doctoral student in the Industrial University Occupational Hygiene program.

Mr. White, CIH: Industrial Hygiene Manager, Better Living Chemical Company.

Ms. Sharp: Legal counsel for Better Living Chemical.

SCENE 1: BLC conference room.

Mr. White: I called this meeting today at the request of Dr. Impinger from Industrial University. He conducted the POHC pilot study under the direction of the Head of the Occupational Hygiene Department, my good friend - Dr. Dose. The preliminary study findings were submitted to me last week.
[lifts a bound document for all to see and drops it on the table]
Professor Impinger, could you please explain your concern to Ms. Sharp? Ms. Sharp is legal counsel for the company.

Dr. Impinger: It's a pleasure to meet you, Ms. Sharp. I think you know already that I want to announce these findings next week at the annual Industrial Hygiene Conference...

Ms. Sharp: *[coolly]*
Yes, professor, but our contract with the University allows us time to review your findings prior to publication. I understand you think 6 months is too long for my client to review the results?

Dr. Impinger: *[Indignant]*
Way too long - 2 weeks is more than enough time to review a 20-page report! The findings suggest more than *twice* the risk of miscarriage among these women as among the general population. This is a significant finding in an epidemiologic study - one we are obligated to communicate to our professional peers.

Dr. Dose: *[clearing his throat and staring at Dr. Impinger]*
Perhaps we should summarize what's happened on the project so far - before we address that *particular* issue. Ms. Sharp, about 6 months ago BLC asked our department to submit a proposal to investigate employee concern about miscarriages on the monomer line. It seems a few women working on the monomer line reported miscarriages during the first year of production.

Mr. White: Since the company physician had not personally examined these women - and all the miscarriages had not been confirmed by private physicians, it is possible these reports are spurious. However, we want to ensure our workers are safe here at BLC, so we decided to investigate.

Ms. Sharp: Wait a minute - I thought POHC had been extensively tested and found to be environmentally safe? Why should these women be getting sick?

Mr. White: POHC *is* both biodegradable and environmentally-safe. However, during manufacture, we add a catalyst to a monomer. The monomer we use has

been around in industry for a long time - with no known health effects. But it has only been used for research - in small quantities and by only a few people at a time. We were the first company to find a valuable application for the monomer - and to start using it in large quantities on a production scale.

Ms. Sharp: So the monomer was never fully tested in the lab for health effects?

Dr. Dose: That's right - so to study the monomer's effects on workers, we initially presented a proposal for a cohort study of all 200 women working here at the plant over the next five years. Corporate management suggested we start on a small scale - that we conduct a pilot study before we commit to a larger study that may prove unnecessary... Patty is a doctoral candidate in our Department. She performed most of the field work. Patty, could you explain the work you did here for the pilot study?

Patty: Well, first I collected breathing zone samples to determine exactly how much monomer the women were breathing.

Ms. Sharp: Right - I looked at those numbers. Did I read the tables correctly? It looked like you only sampled 2 hours during one work day for each worker you sampled.

Patty: That's right. I'm involved in several projects so I only had 2 hours to sample each day - after driving over here and setting up the pumps.

Dr. Impinger: The workers do the same thing all day long - 2 hours is representative of their entire day's exposure. I made the decision that this was sufficient sampling - especially considering the reduced funding and pilot nature of the survey.

Mr. White: Didn't you always sample in the afternoon, Patty?

Patty: Yes, getting over here in the morning wasn't convenient. I have other lab work in the mornings.

Ms. Sharp: Wouldn't exposures be higher in the afternoon? After vapors accumulated in the area all day?

Patty: It's possible - vapors might accumulate during the day. The monomer is not very volatile so there is no special ventilation on the line. However, other work I've done shows concentrations tend to be lower in

the afternoon... but we didn't sample in the morning, so we're not sure what's happening on the monomer line.

Dr. Dose: Industrial hygienists often sample to estimate worse-case situations. Since this was just a preliminary survey, I think this sampling scheme is acceptable, Ms. Sharp.

Ms. Sharp: But we don't really know for sure what the average exposures are, do we?
[pauses, and looks at the professors]
I noted also that only 5 workers were sampled; how many women work on the monomer line?

Mr. White: Oh, it varies, but close to half our workers have been assigned to the POHC line this month - that makes about 100 women, on average.

Ms. Sharp: I'm not a scientist, but is it adequate to sample only 5 out of 100 workers?

Dr. Impinger: Again, this was only a pilot study. We were just trying to get a handle on the exposure range. To estimate the risks presented in the report, all the women were classified as "exposed." Their exact exposure wasn't really important.

Dr. Dose: Patty, didn't you also interview the employees?

Patty: Yes. We used a standard reproductive effects questionnaire provided by the American Obstetric Association. There are questions about pregnancy history and prior work exposures. We also added a few specific questions about the monomer line.

Mr. White: Production levels have been extremely high for POHC. The pressure is on to keep quality levels up... did you look at stress as a possible confounder?

Dr. Dose: I remember we did discuss that at the initial meeting. Dr. Impinger?

Dr. Impinger: The standard reproductive effects questionnaire does not include stress-related questions. We planned to develop these and include them in the full cohort study questionnaire.

Mr. White: So you *didn't* ask about stress?

Dr. Impinger: No, we didn't.

Ms. Sharp: I still don't understand why you are so fired up to announce to the world that the monomer *causes* reproductive effects? I mean, we've brought up one other possibility, and there may be *many* others, right?

Dr. Dose: That's what the full cohort study is designed to show.

Mr. White: Why can't we wait until the full study is complete to announce the findings? When we are more confident in the results?

Dr. Impinger: Because the monomer is being used by more and more plastics manufacturers. Since the formulation for POHC was released in February, it's the only packaging material being used and demand is not even close to being met.

[exasperated]

Besides, it's our responsibility to alert them to any *potential* problem. We have an *obligation* to advise those affected workers regarding health risks.

Dr. Dose: It seems the issue here is whether the facts justify serious talk about health risks. Dr. Impinger, should we alarm people needlessly when there may be no problem? Aren't we also obligated to base our professional opinions on good science?

Dr. Impinger: When we make the announcement, we'll emphasize the limitations of the survey results.

Ms. Sharp: *My* responsibility is to Better Living Chemical. I know people do not remember the small print - they won't even read it. They'll all walk away believing the monomer is unsafe. I'm also wondering... if you are so confident in the results of the survey, if you're willing to announce the results to the world, why do you even need to perform the full study?

Dr. Dose: *[worried]*

Any final conclusions should be based on a rigorous investigation - the survey results give grounds to justify continuing the project. Myself, I'm not sure that these data give a basis for any firm conclusions -

[to Dr. Impinger]

-and early announcement of findings may bias the workers' responses during the full study.

- Patty: Excuse me... I guess I should point out that only women on the monomer line were questioned and sampled. We didn't ask women working in other areas about their pregnancy history. Also, in our risk calculations, we assumed no exposure in other areas of the plant.
- Mr. White: Oh? I thought the increased risk was based on comparing exposed and unexposed women in the plant.
- Dr. Dose: That's what we planned to do initially. Since the full project wasn't funded, we had to cut back. We were only able to compare rates among the monomer line workers to rates in the general population.
- Ms. Sharp: Couldn't the vapors move into other areas of the plant and expose other women? Wouldn't your risk estimates be more valid if compared to other production workers than all women in the general population?
- Dr. Impinger: Yes, of course they would, but as I said, we didn't have the money to do that —
[impatient - to Mr. White and Ms. Sharp]
back to the survey report - why can't you complete your review in 2 weeks?
- Ms. Sharp: A lot of busy people need to read the report - the CEO, his science advisors, other attorneys... After we understand what the results *mean*, we have to work out a strategy for presenting the results to those who need to know - and clearly stating the limitations of the survey.
- Dr. Impinger: And in the meantime, workers continue to be exposed!
- Mr. White: Well, here at this plant, we have started rotating women between shipping and the monomer line to reduce exposures - and we've installed some dilution ventilation - just as a precaution - while we wait for the final results.
- Ms. Sharp: Our contract gives us the right to review findings. There is no time frame stipulated for that review.
- Dr. Dose: She's right. It appears they can take as long as they like...

Mr. White: Well, if there's no more technical discussion, let's adjourn. We'll call you when we've finished the review.

Dr. Dose: In the meantime, we'll revise our proposal incorporating the results and lessons learned during the quantitative survey.

Ms. Sharp: I doubt funding for the full study will even be considered before the review is complete.

Mr. White: *[to Dr. Dose]*
I'll see you at the golf course Saturday?

Dr. Dose: I'll be there!

SCENE 2: In Dr. Dose's car on the way back to Industrial University.

Dr. Dose: *[to Dr. Impinger]*
Say, don't you think you were a bit confrontational?

Dr. Impinger: Well, I couldn't help it. They seem to take pleasure in lording their financial power over us.

Dr. Dose: Better Living has provided funding to our program for 15 years. They are committed to fully researching their products for safety. I don't appreciate your implication.
[more sensitively]
Is your upcoming tenure meeting influencing your reaction, by any chance?

Dr. Impinger: I definitely need additional publications - this project has fully occupied my time for the last 6 months - it's all I have right now.

Patty: Dr. Impinger, aren't you scheduled to present the findings during a technical session at the conference?

Dr. Impinger: I stated in the abstract that I would present the results. I guess I'll have to cancel the presentation.

Dr. Dose: You could just present the methods. Our peers might have some interesting thoughts on how to design the full study.

Patty: Isn't the *important* point here is whether we really feel the evidence is strong enough to warn users of the monomer about the reproductive effects? Don't we have to let people know if we have the evidence?

Dr. Dose: Patty, you know that your stipend is being paid through this grant. If they decide not to extend the project, we won't be able to support you next semester.

Patty: Maybe we should at least call other manufacturers and just ask if they've noticed any increases in miscarriages?

Dr. Impinger: That might tip them off to a possible study - and someone might be able to publish before we can! Then my paper would be useless.

Dr. Dose: Also, calling other manufacturers might put us in a legal situation with BLC. Like Ms. Sharp said - we signed a contract - releasing the results before they OK it would set us up for a lawsuit.

Dr. Impinger: I think not publishing sets us up for one too.

Dr. Dose: How so? I'm not aware that we have any legal obligations to anyone besides the company - but if you publish without my approval the University isn't going to defend you.

Dr. Impinger: You've done a lot of consulting for them, haven't you? Any chance that's swaying *your* views on the matter?

Dr. Dose: *[put off]*
I don't think that's the point here...

Patty: Dr. Dose, I didn't think you were allowed to perform consulting as a faculty member.

Dr. Dose: The faculty are allowed to spend approximately 10% of their time on outside consulting. It's in their contracts. I used to do a fair amount of work for BLC. Now that I'm department head, I'm not allowed to consult anymore.

Dr. Impinger: *[to Dr. Dose]*

Weren't you just in Mexico looking at one of BLC's plants?

Dr. Dose: While I was on vacation, I did evaluate the Hazard Communication Program in Leon. It's not like they paid me for my services, though.

Dr. Impinger: I heard they paid airfare for you and your wife.

Dr. Dose: My wife is a nurse. She reviewed the Medical Program at the plant. The airfare was just to cover travel expenses, not to pay for the consulting.

Patty: What a deal! - *[pause]*
[hesitantly]

It may be a little late to bring this up, but I came across something in an environmental law text about how a company is required to submit test data and get a permit from the Federal government before bringing a new chemical into production. I didn't read closely - I think it was about the "Toxics Management Act." Do you think BLC has done all that?

Dr. Dose: That's the Toxic Substances Control Act, Patty. It's administered by EPA, not OSHA. It covers environmental releases, but we're talking an occupational situation here; I don't think it applies. Besides, POHC is not a new chemical; it's been around for years.

Dr. Impinger: That's a good question, Patty.

[pause]

Now that I think about it, I seem to remember that the provisions cover "health" as well as "environment." - and as all these statutes do, it contains language about coordination among agencies, when situations covered by other laws come up. I'm not so sure it's completely irrelevant.

Dr. Dose: White has assured us that POHC is environmentally safe; I think we can assume that BLC has met their legal requirements. They want epidemiological data to be more certain and reassure their employees.

Dr. Impinger: All the more reason for them to fund the study! I don't know what they think they're accomplishing by stonewalling and sitting on the data.

Patty: I could run down to the law library and read over the statute - just to get an idea what the requirements are.

Dr. Dose: Sure, why don't you, Patty - if you have time, but I don't think it'll change anything

SCENE 3: Mr. White's Office.

Mr. White: Impinger's a loose cannon... I don't believe he's going to wait 6 months before he tells someone these findings.

Ms. Sharp: We can't let them spread erroneous information!
[undertone]
The employees could sue us and the company could lose a bundle. Management wants this kept in house, until they have a chance to figure out if there's a real problem and how to handle it. Between you and me - if you really don't think Impinger's reliable you might think about updating your resume.

Mr. White: You know, I'm not at all certain that they aren't on to something...
[contemplative]
I had to side with you, and the company, in the meeting. But I've been here as an industrial hygienist for 25 years and I've only heard of one miscarriage prior to that monomer line start-up.

Ms. Sharp: But you were the one who brought up stress as a possible confounder?!

Mr. White: I believe it probably is, but we've always worked our employees hard here. Production of every chemical we make is accelerated beyond other facility rates. Most of those women have worked here for years. Stress is nothing new to them.

Ms. Sharp: You may not be aware that Personnel has received a lot of petty complaints this year. There has been a freeze on pay increases for the line workers at this plant. The miscarriage complaints may just be the employees' way of letting us know they're not happy.

Mr. White: Is that right? I hadn't heard about a pay freeze. That could cause some trouble. They've never had a pay freeze here before.

Ms. Sharp: There seem to a lot of unanswered questions that place doubt on the findings....If they publish without our okay, we'll have to sue the University and both Dose and Impinger individually for breach of contract.

Mr. White: *[shaking his head]*
Dose and I have been friends for a long time. I'd sure hate to lose my golf partner.

Questions on the Scenario

MedPartners Corporation has outlined a series of considerations designed to provide structure to ethical deliberations. The steps are designed to guide an employee in thinking through an ethical dilemma and coming to a decision. The process is called T.R.U.S.T. and contains five steps:

T Think about the situation objectively
Clearly understand the situation
Know the facts
Identify the real issues

R Recognize and Analyze Motivations
If the situation troubles you, ask yourself why
Consider the other party's motivations

U Understand Applicable Policies and Laws
Know whom and when to ask for guidance

S Satisfy the Headline Test
Would you feel comfortable seeing your action reported in the news
How might your family and colleagues see your decision?

T Take Responsibility for Your Actions
Make an appropriate choice and act accordingly
Remember that you are accountable for the outcome of your decisions

The questions are based on the scenario and designed to follow the T.R.U.S.T. process. However, questions specific to "R" were not included for two reasons. Imputing the motives of others is a natural reaction in a difficult situation, but it is guesswork at best. More importantly, guessing at the motives of others does little to aid you in reaching your own decision.

Think Objectively and Get the Facts. Focus on the Real Issues.

Identify each of the following as true or "factual" (T), false or "not factual" (F), "Unknown"(U) or "Interpretation" (I). You may consider an interpretation as correct or incorrect, or more or less valid, but for this question focus on distinguishing factual points from interpretations, and valid assertions of fact from those that are invalid or questionable.

- A ___ POHC causes miscarriages.
- B ___ The monomer has been extensively studied for health effects.
- C ___ BLC does not care about its employees' welfare.
- D ___ Women working in the plant have reported miscarriages.
- E ___ The pilot study data are sufficient to adequately characterize exposures.
- F ___ Dr. Impinger has an obligation to publish his findings at the conference.
- G ___ Women working in the plant have been exposed to the monomer.
- H ___ Reports of miscarriages are merely indirect expressions of workers' dissatisfaction with other issues.
- I ___ Women not on the monomer line have experienced miscarriages.
- J ___ A full-scale cohort study is unnecessary.
- K ___ The dilution ventilation and worker rotation have reduced exposures to below levels of concern.

Identify the most critical issue related to the ethics of this case:

Whether the release of potentially erroneous information would prove damaging to the company.
Whether Dr. Impinger can publish first.
Whether the preliminary data are sufficiently compelling to create an imperative to release them.
Whether the results justify funding for a full cohort study.
Whether the company grants permission to publish.

Understand the Code of Ethics and Applicable Laws.

Which principles or laws, if any, have been violated by Mr. White?

A Canon 1, conformance to recognized scientific principles.
Canon 2, factual counseling of affected parties.
OSHA Permissible Exposure Limit for POHC.
Canon 4, compromise of judgment or conflict of interest.
Toxic Substances Control Act.
OSHA general duty clause.

Which Canons, if any, have been violated by Dr. Dose?

Canon 5, restriction of services to areas of competence.
Canon 3, confidentiality of personal and business information.
Canon 1, conformance to recognized scientific principles.
Canon 4, compromise of judgment or conflict of interest.

**In deciding on a course of action, which canons or laws apply to the University hygienists?
Which of these appear to conflict?**

Common law of contracts.
Canon 2, factual counseling of affected parties.
Common law of negligence.
Canon 3, confidentiality of personal and business information.
Toxic Substances Control Act.

Satisfy the Headline Test.

Based on the action in the scenario and your projection of how events might unfold, what might be the headline most likely to appear in the local paper?

"Workplace fumes linked to miscarriage: IU researchers draw attention to hazardous new chemical."
"BLC protects profits not workers: IU researchers involved in cover-up."
"OSHA to take strong steps - local chemical company to pay heavy fine."
"Outraged women go to court - IU department, faculty named in negligence suit."
"BLC shows its conscience - production of new product curtailed until safety ensured."
No headline is likely to appear.
Take a responsible course of action.

7. If BLC denies permission to publish and the professors shelve the study results, what is an ethical course of action for Patty to take?

"I'm just the technician. My job was to collect data. Deciding what the results mean, if anything, and what to do about them is not my responsibility."

“Dr. Impinger tried to talk impressive, but now he’s just going to sit on the data. It’s up to me to notify the workers somehow.”

“The workers already know about the concerns with this chemical. They made the complaints. They know that I sampled, and that I interviewed, asking specifically about reproductive problems. They can see that they’re being rotated, and that new fans were installed. We don’t need to patronize them - if they still have concerns they can decide for themselves what action to take. They don’t have to keep working there.”

“Somebody’s got to do something - maybe I can persuade Dr. Impinger to counsel the employees. If that doesn’t work, I could make an anonymous call to OSHA or EPA. I could make the call from a pay phone near the plant and pose as an employee - that would sound plausible. They might suspect it was one of us but they wouldn’t be able to prove anything.”

“It’s like Dr. Dose and Mr. White said: the pilot study results are too uncertain and inconclusive to alarm workers or justify interventions. If we perform the full study, we can collect more adequate data and control for confounding. Then we can reevaluate the question of whether a real problem exists.

“They’re using those women as guinea pigs. Even if they fund the study I can’t continue to be a part of it until they meet their notification and testing requirements. I can find a job or another project if I have to.”

If Mr. White decides it is advisable to release some information to employees, what would be necessary to fulfill the requirements of Canon 2, regarding factual counseling of affected parties?

“We can make results available, minus interpretation or recommendations. That’s all that an MSDS provides.”

“We need to provide results, our best interpretation of their significance and a description of the precautions we’ve taken.”

“We need to counsel each woman individually regarding her work experience, exposure, potential effects and plans to have children.”

“If we believe that the precautions we’ve taken are sufficient, we can conclude that any potential health risks are substantially eliminated. That precludes an obligation to provide further information.”

Answers to Scenario Questions

1. Questions of Fact and Interpretation.

I: This may be subsequently demonstrated but at present remains speculative.

F: Mr. White doesn’t say as much but from the script we can assume that the monomer has not been tested.

I:

T,U: The factual occurrence of the miscarriages is not positively certain as not all reports were confirmed but it is prudent to assume that at least some of the reports are accurate at least until the monomer is proven safe.

I,U: This sampling is not adequate to characterize exposures. The sample size is too small and the sample duration too short. This question is not crucial to the ethical dilemma, as the sampling did not drive the risk estimates.

F: Dr. Impinger is under no legal or ethical obligation to publish the findings in a conference, journal or other scientific forum. In some cases an industrial hygienist may be obligated to disclose information

to affected parties or the authorities, but in such cases, publication in itself is unlikely to meet the obligation. Publication does not insure that affected parties will be directly and adequately informed. Such an obligation is also contingent on an interpretation by the hygienist that the risk to safety or health is “overriding” (Canon 3) or “unreasonable” (Toxic Substances Control Act).

T: The exact magnitude of exposure and its consequences remain in question, but the fact of exposure itself has been established.

I: How plausible is it that women who have undergone miscarriages would use a personal emotional trauma to express dissatisfaction about pay issues at work?

U: This question has not been investigated.

I: This conclusion is premature.

U: The adequacy of ventilation is assessed in relation to a target concentration. An established TLV is recommended for this purpose. Safe air concentrations of POHC are unknown and we can assume that no occupational exposure standards or guidelines exist. The extent of protection provided by the precautions taken is therefore unknown.

C The ethical obligations of Mr. White and the University hygienists pivot on this question. Canon 2 imposes an obligation to disclose information to affected parties when necessary to protect health and safety, even when the risk is “potential.” Canon 3 imposes a complementary obligation to maintain confidentiality except when the law or “overriding” health and safety concerns require disclosure. This implies that the information may only be disclosed to those who have a right to it, i.e., clients, employers or those whose health or safety may be at risk. Note that the force of the ethical obligation is contingent upon two levels of interpretation, that of the technical information itself and that of the seriousness of the concern or risk inferred from the technical information. Such an interpretation also informs specific legal obligations to disclose information, as shown by the following example from the Toxic Substances Control Act:

Any person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the Administrator (of EPA)... (ToSCA 15 U.S.C.A. §2607(e)).

A violation is clear for E and debatable for B or F.

E The script suggests that BLC is in violation of the Toxic Substances Control Act, which requires that “any person” submit a minimum 90-day notice and test data to EPA prior to commencement of production of a chemical substance or mixture intended for “a significant new use.” Following submission of the notice of intent to manufacture the chemical, EPA determines whether the new use is “significant.” The criteria applied include the projected volume to be manufactured and the extent to which a use changes or increases the form, duration or magnitude of human or environmental exposure (ToSCA, 15 U.S.C.A. §2604(a)). The script suggests that BLC took a known but untested chemical into large-scale production without meeting these requirements and initiated testing only later when potential problems surfaced.

B Mr. White is arguably in violation of Canon 2, which requires counseling of affected parties regarding potential health risks. A reasonable reading of the Canon is that adoption of specific precautions should trigger an obligation to counsel.

F Whether Mr. White may be considered in violation of the “general duty clause” of the Occupational Safety and Health Act (OSHA) depends on how seriously the apparent risks are viewed. This clause requires that the employer furnish “employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm.” If the initiation and completion of a pilot study constitute “recognition” and subsequent precautions reduce exposure sufficiently, Mr. White is arguably in compliance. If safe concentrations are unknown, however, as in this case, it is difficult to see how BLC can be sure that the workplace is free of the hazard. The potential significance of dermal exposure is also unknown. On the other hand, it is difficult to conclude that use of an untested chemical in itself constitutes violation of the clause. If this were accepted, no manufacturer would be in compliance, given the number of untested compounds in use in industry. Recognition probably requires more than suspicion that a risk may exist; it requires that the hazard is clear or demonstrated with some degree of certainty. Given the uncertainty in the risk estimates, that reports were not confirmed at the time and confounders were not examined and ruled out, BLC is not in clear violation of the General Duty Clause. However, the clear violation of ToSCA requirements obviates the need to consider this question closely.

D Dr. Dose is in violation of Canon 4, in entering and maintaining a relationship with BLC that gives at least the appearance of conflict of interest. Aside from a long-term funding relationship, which is not necessarily questionable in itself, Dr. Dose continues to engage in consulting activity in violation of his terms of employment as Department Head. Financial consideration in the form of travel expenses while on “vacation” is valuable enough to create a presumption that the gift could influence judgment.

All of these Canons or laws require consideration but not all clearly apply. Application is clear for A, C and D and debatable for B and E.

As the script makes clear, the University is under a contractual relationship with BLC not to publish the study findings without permission. This obligation, however, does not relieve the researchers of other legal and ethical obligations.

Canon 2 applies to the researchers but they have met its most obvious requirements by informing Mr. White of their concerns. It can be assumed from the script that the characters are not in a jurisdiction that requires direct disclosure to employees. If the University is named as a third party in a subsequent negligence suit, the fact that the researchers expressed their concerns to BLC is not likely to serve as an

adequate defense. Apparently, BLC has taken precautions but does not intend to disclose information to employees for at least six months. Would direct steps taken to inform employees constitute “publication?” Would they violate the University’s contract? The force of this Canon also depends on interpretation of the term “potential health risk.” The preliminary data does not appear sufficiently compelling to require a direct disclosure to employees at this time.

Negligence applies to the researchers in that they may be liable to third-party suits if the employees are not informed of or protected from the reproductive health risks and substantial harm eventually results. The realization of this liability depends on the legal jurisdiction and the interpretation of difficult technical issues concerning the soundness and significance of the results. The results at the time of the scenario would probably not sustain a negligence claim. If employees continued to experience health effects, the question could become a serious one.

Canon 3 requires the researchers to maintain confidentiality of information concerning the company or its employees unless law or regulation requires disclosure or unless they see the health risks at issue as “overriding”. Do you agree that the concerns are not overriding in this case? However, even in the case of overriding concerns without a clear legal requirement, this Canon appears to prohibit disclosure to any party aside from the client. This appears to conflict with the guidelines for Canon 2, which states that “affected parties” “may include” employees. Given a strict prohibition in Canon 3 and a qualified requirement in Canon 2, the researchers can maintain at least technical compliance with both Canons by avoiding disclosure of any information to any party, including employees, unless BLC grants permission. Are you comfortable with this result? However, compliance with both Canons will not serve as a complete defense against third-party liability as described above.

The Toxic Substances Control Act contains requirements for disclosure of health-related information. Aside from the requirements of §2607(e) mentioned above, §2607(d) requires “any person” who has possession of a health and safety study conducted “by or for such person”, or which is “known to such person” or “reasonably ascertainable by such person” to submit a copy of the study to the Administrator of EPA. The term “any person” in the legal sense applies to any individual or organization, not only the manufacturer. That §2607(e) applies is not clear, given the limitations of the pilot study, i.e., it is not clear that the risk is “substantial.” The requirements of §2607(d) are not contingent on interpretations of significance. Given the limited scope and significance of the pilot study, should it qualify as a “health and safety study” under this section? The requirements of ToSCA are enforceable by citizen suits, meaning that both the researchers and the company could be liable for withholding information, notwithstanding workers’ compensation and third-party relationships.

The most likely headlines to appear are D or perhaps F.

D Given the circumstances in the scenario, it is quite plausible that a suit could be filed, especially if more miscarriages occur among the women on the monomer line. Whether the suit would prevail on the merits is another question but this would not affect the media response at the time the suit was filed. If D appears, B or C may also appear eventually, depending on the outcome.

F If the workers are satisfied by the precautions taken and additional miscarriages are not reported, no news story may emerge.

F Assuming that the new chemical is being produced on a large scale in violation of specific legal requirements under ToSCA §2604(a), the most ethical course of action for Patty is to discontinue involvement in the study. This assumes that the preliminary results do not show “substantial risk,” triggering requirements under ToSCA §2607(e). BLC is unlikely to interrupt production of POHC in order to perform involved and costly tests. If ethical conduct involves compliance with applicable laws, and you cannot influence another party’s actions, is avoiding complicity the ethical course of action? Do you believe that Patty should do more?

B It is necessary to provide interpretation because without it the results are not meaningful to management or employees. If precautions are taken it is ethical to counsel employees concerning the purpose behind them and how they must be applied to be effective. Declining to interpret the results is an abdication of responsibility. The current data are not sufficient to require individual counseling, except for the women who experienced miscarriages.