

May 17, 2005

Lester M. Crawford, D.V.M., Ph.D.
Acting Commissioner
U.S. Food and Drug Administration
Parklawn Building
5600 Fishers Ln.
Rockville, MD 20857

Dear Dr. Crawford:

We are writing to share with you the findings of our 11-month investigation at Covance Laboratories, Inc., located at 9200 Leesburg Pike, Vienna, VA 22182. Our investigation has uncovered serious and chronic violations of the federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. §§ 301 *et seq.*) and implementing regulations that govern laboratory practices for nonclinical laboratory studies (21 C.F.R. §§ 58.1 *et seq.*). Simply stated, standard practices at Covance—including gratuitous physical and psychological abuse of primates—undermine the quality and integrity of data generated by the studies and thus undermine the purpose of the FDCA. We respectfully request that the FDA investigate this matter and take appropriate enforcement action.

In general, the PETA investigation reveals that employees are not supervised adequately and that standard operating procedures, as well as the requirements of study protocols, are routinely breached or simply ignored by Covance. Enclosed you will find a more than 200-page complaint to the U.S. Department of Agriculture (USDA) alleging hundreds of violations of the federal Animal Welfare Act. Under separate cover you will receive DVDs that set forth evidence of many of these violations. Many of the incidents described in the USDA complaint and further documented in the DVDs also constitute violations of the FDCA.

The following is a representative list of violations of the FDCA; please note that it is not an exhaustive list by any means. Each general class of violation (denoted by roman numerals) is followed by the relevant regulations and representative excerpts from the investigator's log (in italics), which describe the violations:

- I. GRATUITOUS PHYSICAL AND PSYCHOLOGICAL ABUSE OF PRIMATES AT COVANCE DEMONSTRATES THAT COVANCE SANCTIONS BEHAVIOR THAT FALLS OUTSIDE THE PARAMETERS OF STUDY PROTOCOLS, IN VIOLATION OF 21 C.F.R. §§ 58.120 AND 58.130.

21 C.F.R. § 58.120(a); (b): Each study shall have an approved written protocol that clearly indicates the objectives and all methods for the conduct of the study. ... All changes in or revisions of an approved protocol and the reasons



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therefore shall be documented, signed by the study director, dated, and maintained with the protocol.

21 C.F.R. § 58.130(a); (b): The nonclinical laboratory study shall be conducted in accordance with the protocol ... [and] the test systems [e.g., primates] shall be monitored in conformity with the protocol.

9/10/04

Today I saw C intentionally taunt some of the training monkeys. There was a net (used to catch loose monkeys) in the room because one of the males had gotten loose and they could not catch him by hand. All of the monkeys are very afraid of the net and when C picked it up, they screamed and barked. C intentionally took the net and shook it several times at Big Boy (who was in his cage) and told him, "I'm gonna get you." C would then step back from the cage and then lunge forward towards Big Boy to rile him up.

10/13/04

K caught monkeys for the 6131-456 study today while I dosed. He was struggling hard with some of the monkeys and he was being very cruel. While trying to restrain one of the males, he slammed him on the concrete floor, and then was practically strangling him while holding his head for dosing.

12/8/04

Q continued to torment the animals today. At one point when monkeys were being bled on C's 6824-122 study, I saw Q holding a monkey in a restraint tube, and as he was holding off the animal's vein, he intentionally provoked and scared the animal by forcing his face near the tubed monkey's face and making frightening faces and pestering the animal. As usual, I yelled at him to leave the animal alone, at which time Q promptly returned the monkey to his cage, and said to me, "I feel much better," implying that he gets his kicks and relieves stress by tormenting the animals. I told him that the monkey certainly didn't feel better, and that he should not treat the animals that way. R told us that from group 3 on, these monkeys feel like death with no muscle tone and they're cold.

Clearly, none of the gratuitous abuse witnessed by the investigator and described above or in the attached USDA complaint is sanctioned or would ever be sanctioned by a study protocol, precisely because such physical and psychological abuse jeopardizes the quality and the integrity of the data.

II. COVANCE'S STANDARD OPERATING PROCEDURES, INCLUDING BUT NOT LIMITED TO THOSE REGARDING THE CARE OF ANIMALS, ARE INADEQUATE OR DISREGARDED ON A REGULAR BASIS IN VIOLATION OF 21 C.F.R. §§ 58.90 AND 58.81.

21 C.F.R. § 58.90(a): There shall be standard operating procedures for the housing, feeding, handling, and care of the animals.

21 C.F.R. § 58.81: A testing facility shall have standard operating procedures in writing setting forth nonclinical laboratory study methods that management is satisfied are adequate to insure the quality and integrity of the data generated in the course of a study. All deviations in a study from standard operating procedures shall be authorized by the study director and shall be documented in the raw data. Significant changes in established standard operating procedures shall be properly authorized in writing by management. Standard operating procedures shall be established for, but not limited to, the following: animal room preparation; animal care; receipt, identification, storage, handling, mixing and method of sampling of the test and control articles; test system observations; laboratory tests; handling of animals found moribund or dead during study; necropsy of animals or postmortem examination of animals; collection and identification of specimens; histopathology; data handling, storage, and retrieval; maintenance and calibration of equipment; transfer, proper placement, and identification of animals.

6/2/04

I did the dog AM mortality checks this morning. He said that the dogs were very agitated because they did not have any food. In the afternoon, I went to see if there were feeders filled up for the dogs. There were no prepared feeders and there were no clean feeders for us to do the job ourselves.

7/14/04

While handing out some bananas this afternoon, I entered a room that had just been cleaned. One of the monkeys was drenched from head to toe. She sat hunched over on the cold metal perch in the back of her cage. Both the dog cages and the monkey cages are cleaned while the animals are still inside.

8/2/04

One of the monkeys received burns on his/her nipple and chest from the alligator clips used for the first ECG. I mentioned this fact to K and he simply acknowledged that the monkey had burns. During the second ECG, I once again commented about the burns, but K did not seem concerned. I later mentioned this problem to J. He admitted that this often happens due to the electricity from the ECG machine. J said that the machine could be grounded, but when he looked for a grounding clip on the ECG machine, he found that there was none.

9/13/04

I read several SOPs that were updated and needed to be signed off in my training file. One of the SOPs discussed Covance's enrichment program and says that the primates are provided with various food enrichment on a daily basis. The items listed included cereal, peanuts, graham crackers, saltines and many other treats. I read this section aloud to C and asked her what the real story was behind this, given that I have never

seen any of these food items at Covance. She said that Covance would not pay for any of these items and that the only way the monkeys would get any of the treats would be if the technicians bought them and received permission from the study director to give them out. She said that most of the study directors would not allow these foods to be given to the animals anyways. C also said that only a couple of months ago, they began giving out fruit other than apples and that the technicians had to fight for the different fruits such as bananas, oranges and grapes. In reality, if none of these items are ever used, it is deceptive for Covance to list them in the SOP as if they were done on a daily basis.

11/1/04

Both C and J said that we are probably going to put all of the animals down before AAALAC arrives because they think that AAALAC will definitely shut the study down because the animals are suffering and it is inhumane, and that Covance will have problems because of this.

Obviously, standard operating procedures at Covance are either inadequate to meet the requirements of federal regulations or they are violated on a regular basis, thereby compromising the quality and the integrity of the data.

III. COVANCE'S PERSONNEL ARE INADEQUATELY DIRECTED AND SUPERVISED, AS WELL AS INADEQUATELY SKILLED AND TRAINED, IN VIOLATION OF 21 C.F.R. §§ 58.29 AND 58.31.

21 C.F.R. § 58.29(a): Each individual engaged in the conduct of or responsible for the supervision of a nonclinical laboratory study shall have education, training, and experience, or combination thereof, to enable that individual to perform the assigned functions.

As a preliminary matter, please note that the incidents of gratuitous physical and psychological violence at Covance, as set forth in Section I, are also evidence of improper and inadequate training of technicians. However, the incompetence does not end with the technicians. Serious ineptitude by one veterinarian in particular was apparent during our investigator's time at Covance. For example, in early December 2004, a macaque broke his arm when it became wedged in the bars of his cage. The veterinarian (and other supervisors) left the monkey untreated for nearly four days until a junior veterinarian returned to the facility. Only then was the animal euthanized as a result of the serious nature of the injury. Technicians referred to this veterinarian as "Mr. Let's Wait and See."

Moreover, when the PETA investigator was trained at Covance's Vienna, Va., facility, she and other new technicians were shown the investigation video filmed by the British Union for the Abolition of Vivisection at Covance's Münster, Germany, laboratory. The trainer told this group of new staffers that only those who didn't work with nonhuman primates would think that there was anything wrong with the actions shown on the German undercover video. Those actions included screaming at and threatening

monkeys, cursing at the animals, forcing them to “dance” and otherwise mocking them, and shaking them in the air when they were less than cooperative. The Covance trainer told our investigator and the other technicians that monkeys “like to dance.” It is no surprise that we found identical behavior at the Vienna, Va., Covance laboratory.

5/5/04

One dog who I examined had severe tartar buildup all the way up to her canines. I showed her teeth to R and asked if they were in bad enough condition for me to put a remark in the computer and request a cleaning. R told me her teeth probably weren't dirty enough, but he did not know how dirty they should be before I should enter a comment in the computer database. He said that he would “check on this.” Another dog had swollen pads from walking on the slatted metal cage floors. I showed R the dog's feet and asked if they were swollen. He said no, the dog just had big feet. Even an employee who has worked at Covance for 34 years cannot recognize these signs of neglect.

5/20/04

I was asked to anesthetize a group of monkeys even though I have not been certified to do so.

6/9/04

Many of the monkeys had hematomas and bruised calves where they were injected multiple times over the past week. Their veins would also “blow out” because there were already holes in the vein, or the technician went through the vein while trying to inject. J had a difficult time injecting the monkeys today. At one point, I saw her enter a vein and reposition the needle more than 5 times while trying to inject one of the monkeys.

6/23/04

She said that she helped T treat a sick monkey in one of the quarantine rooms yesterday. J explained that T took the “Quarantine” signs off of the doors to the room when they went in so that they did not have to put extra garb on (Tyvek suit, extra gloves, a mask you have been fitted for and a pair of shoe covers—a violation of USDA quarantine procedures). The quarantine monkeys had never been caught before and were very scared when J tried to catch them. J said that she got bloody feces on her coveralls (since she was not wearing her Tyvek suit). This is very dangerous since she could infect the rest of the monkeys (or herself) if they were to come in contact with infected feces/blood.

7/1/04

When I arrived to Covance for the 12 hour TKs after eating at home, I found out that the other technicians had gone out to eat. They all smelled of alcohol and were very giddy. J told me that they had a few drinks with dinner. I can't imagine showing up to do blood collections after drinking alcohol.

8/18/04

J had the ECG machine hooked up out in the hallway, and as usual, it was not grounded. During our training with R, we were never shown how to or told to ground the machine—people clearly do not care if the monkeys are burned while having ECGs.

10/26/04

J told me that J killed one of the monkeys in grease pit on Sunday by aspirating him. The dead monkey was one of my favorites in the room—he was a real sweetheart. J said that he threw up a lot when J inserted the tube into his stomach, and that he suffered, dying for almost 45 minutes. J said that when it happened, they took the monkey and held him by his feet and shook him in the hopes that some of the fluid would come out of his lungs (as S has recommended doing), but only bloody froth came out. I believe that H was doing surgeries in the room next door, so the technicians had her look at the monkey. I did not receive any details about what she did, but assume that she did nothing and let the monkey slowly die since there was no way to stop the aspiration. This is the second monkey in grease pit that has died from being aspirated.

12/8/04

K and S joked to S about non-GLP studies being great. K said he had a compound that was expired by 45 minutes and D who was the study director said to just go ahead and use it.

The incompetence of technicians, supervisors, and veterinarians at Covance is apparent throughout the incidents documented above and in innumerable other incidents set forth in the USDA complaint. The extent of the lack of adequate skills and supervision is inexcusable, and it cannot help but negatively impact the quality and the integrity of the data at issue.

IV. COVANCE’S STUDY DIRECTORS FAIL TO MEET THEIR DUTIES TO ENSURE THE QUALITY AND INTEGRITY OF DATA, AS WELL AS COMPLIANCE WITH APPLICABLE REGULATIONS, IN VIOLATION OF 21 C.F.R. § 58.33.

21 C.F.R. § 58.33(b): The study director shall assure that ... all experimental data, including observations of unanticipated responses of the test system [the primates] are accurately recorded and verified.

21 C.F.R. § 58.33(c): The study director shall assure that ... unforeseen circumstances that may affect the quality and integrity of the nonclinical laboratory study are noted when they occur, and corrective action is taken and documented.

21 C.F.R. § 58.33(e): The study director shall assure that ... all applicable good laboratory practices are followed.

12/21/04

P, the study director, was in the room and observed J being aggressive and yelling at the monkeys as he was catching them. One example of something that he screamed at a monkey who he struggled to rip from his cage was, "You bastard—get out here!" P observed J's inappropriate handling of the animals, but did not say a word or so much as flinch.

8/20/04

I had to leave T's study before it was over. I later found out that one of the monkeys was found to have had a large laceration on one of her legs. I was told that the client was present and saw the condition of the monkey's leg. A vet was also called in to evaluate the wound, as was K, the study director. I was told by multiple people that the wound was very big and deep and that it had become necrotic—exposing tissue, tendons and nerves. Apparently the client felt that one explanation for this problem may have been that the compound leaked out of the vein and dispersed subcutaneously instead of IV. Even though the monkey was examined by the vet, study director, and client, she was still kept alive instead of being euthanized.

9/17/04

J told me about A's study on which there was a sick monkey about to be euthanized. A was going to draw blood and take tissue but the study director, M told him not to bother, that the protocol required dead animals to simply be discarded. A proved to her that the protocol actually required tissue samples. She didn't even know the protocol.

After a few minutes, the sick monkey became recumbent on the bottom of his cage and another monkey began having seizures. I was horrified to see the poor monkey writhing in her cage and in her restraint tube as blood was being collected (even though she was so sick!). One of the technicians called the vet and study director. Almost 20 minutes later, [the veterinarian] showed up to look at the convulsing monkey. He said that she needed to be euthanized because she was recumbent, had dilated pupils and her eyes were not tracking and he asked someone to get the euthanasia solution. Shortly after, M, the study director showed up along with the toxicologist to look at the monkey. Once M arrived, she looked at the monkey and told [the veterinarian] that the monkey had a "strong heartbeat" and that she wanted to wait 20 minutes and come back to check on her!

11/1/04

I discussed the conditions of the rhesus with H. She said that both she and M told [the client] that they should wait 3 weeks after surgery until the monkeys were irradiated, but that their advice was ignored, and the client waited only 10 days. She said that [the client] was late in getting ACUC approval for the telemetry surgeries so she could not

implant the telemetry devices until later, and the irradiation date was not moved back. H [a veterinarian] expressed concern that the monkeys may not have even received a lethal dose of radiation because the monkeys on the previous study (which was not a lethal dose) did worse than the monkeys on the current study. One group 2 female and one group 1 female have been euthanized, and one group 1 female has died. H told me that some of the holes on the monkey's stomachs have started to close up a little bit and that the monkeys are going to be euthanized on the 17th instead of the 18th. She said that #74, 80, and 69 are the worst off and that today she's going to sedate all of them and finally take their collars off. It looks like the study did not prove anything about [the client's] compound and that the study will probably have to be run again.

11/26/04

H [a veterinarian] told me that she still doesn't know what caused the death of the monkey who died on Nov. 11 who J found dead in her cage (the monkey with the puffy face). She said that she asked for permission to do blood work on these animals but was denied. "It's hard to practice medicine when I can't run any tests ... you have to get the study director's approval." She told me that she had previously wanted to do blood work on these animals but that she was told to wait and see if they got better. H and I discussed the group 2 male monkey who wheezes. H said he has been sick—wheezing and has had a swollen nose—ever since he arrived. He was placed on antibiotics when he first got here because he had a fever.

As the incidents described above and in other sections demonstrate, study directors at Covance often appear to be more concerned with pacifying clients than with taking actions that will ensure compliance with federal regulations.

V. COVANCE FAILS TO ADEQUATELY EVALUATE THE HEALTH STATUS OF NEW ANIMALS AND USES ILL OR DISEASED ANIMALS IN STUDIES, IN VIOLATION OF 21 C.F.R. § 58.90.

21 C.F.R. § 58.90(b): All newly received animals from outside sources shall be isolated and their health status shall be evaluated in accordance with acceptable veterinary medical practice.

21 C.F.R. § 58.90(c): At the initiation of a nonclinical laboratory study, animals shall be free of any disease or condition that might interfere with the purpose or conduct of the study. If, during the course of the study, the animals contract such a disease or condition, the diseased animals shall be isolated, if necessary.

5/20/04

When T performed physicals on the monkeys, she scarcely ran her hands down their stomachs and backs, looked at their teeth, and recorded that they were normal. Many of them had rotten, black baby teeth, were very thin, had deformed or missing fingers, and had terrible diarrhea.

2/15/05

Today I learned that when the monkeys in E's 6131-456 study recently underwent clinpath collections, blood test results revealed that a group 2 female named Big Momma is infected with malaria. C said she wasn't surprised because "that whole shipment was a malaria shipment." She said that some were put on studies and some were put in stock. E thinks this explains the lung problems in 456. He said that two of the monkeys who were put in stock got really sick and were euthanized. The fact that this monkey has malaria may also explain some of the respiratory problems found in the other monkeys, as malaria can cause lung problems. Big Momma was not killed as part of the pre-study sac, but instead, is still on study.

The investigation log notes and video are replete with evidence of animals who were ill or diseased when they arrived at Covance yet were placed in studies. Dozens of examples of macaques who arrived with rampant diarrhea but who were treated only symptomatically are discussed in the unedited video. Obviously, such disregard for the health status of the animals compromises the quality and integrity of the data at issue.

VI. COVANCE FAILS TO ADEQUATELY IDENTIFY PRIMATES, IN VIOLATION OF 21 C.F.R. § 58.90(d).

21 C.F.R. § 58.90(d): Warm-blooded animals ... used in laboratory procedures that require manipulations and observations over an extended period of time or in studies that require the animals to be removed from and returned to their home cages for any reason (e.g., cage cleaning, treatment, etc.), shall receive proper identification.

2/9/05

As I was leaving work today, some of the techs were randomizing monkeys for J's 7602-105 [client name] study, which begins tomorrow. When two of the monkeys' microchips were scanned, the ID numbers that came up did not match the ID numbers on these animals' cages, which would be yet another sloppy mistake made by R when these monkeys were worked up from quarantine. S had already left for the day, and none of the techs knew what to do, as pre-study data (from blood and urine collections, body weights, etc.) has already been generated from these monkeys, and it is essential that the proper data be matched to the appropriate animal.

For obvious reasons, this kind of ineptitude is a direct violation of federal regulations. Given the level of general incompetence demonstrated at Covance, it is likely that this is not an isolated incident.

VII. COVANCE FAILS TO MAINTAIN ACCURATE RECORDS AND FALSIFIES INFORMATION IN RECORDS IN VIOLATION OF 21 C.F.R. §§ 58.130 AND 58.185.

21 C.F.R. § 58.130(e): Any change in [data] entries shall be made so as not to obscure the original entry [and] shall indicate the reason for such change.

21 C.F.R. § 58.185: A final report shall be prepared for each nonclinical laboratory study and shall include ... a description of all circumstances that may have affected the quality or integrity of the data.

12/8/04

Today during lunch, E told D, R, and me the latest news regarding the three monkeys who have died/were found moribund and euthanized in his 6131-456 study (a group 3 female was found dead in her cage on 11/11, and a group 3 male and group 4 female were euthanized on 11/26). According to E (based on the necropsy results), the monkey who was found dead "had a massive bacterial blood infection, but they don't know how it got it" and with regards to "the other two [who were euthanized and found to have hardened lungs], they couldn't find anything, so they're saying, 'Oh, they died from pneumonia from a gavage error.'" J aptly replied, "Bullshit." E said that a Covance stock monkey who was never dosed and recently got sick and had to be euthanized was found during necropsy to have had the very same lung problems exhibited by the 3 dead animals from the study, "but they don't want to tell the client that [because that suggests that Covance is using sick animals in the client's study]." E said that in the study, 7 monkeys were rejected (I do not know any details, but this could be for reasons related to values found during clinpath, urine collection or ECGs) and 2 died before the study started (I am not aware of any details related to the circumstances of these deaths), and that Covance wants to keep the truth from the client, because if [client name] knew that sick animals were being used, "they'd run that whole study over [at Covance's expense], so [Covance is] saying they may just take the hit and say it was a gavage error [that killed the animals]." R said that yesterday, another monkey was found to have had bacteria in the colon, but I am unsure as to which animal she is referring to.

7/26/04

Today I spent a large amount of time preparing for study 7456-117. I have been put in charge of this study even though I am not supposed to have any studies yet. I am supposed to run a "mock study" headed by R before I am even a "backup" technician on a study. S told me that he would put me down as the backup tech on this study but that I would really be the "head tech."

7/28/04

E and J, two techs who started 2 weeks after I did, have finally been released from training. E asked me some questions about the evening room checks (referred to as "morts," as in mortality check) as well as commingling and uncommingling the monkeys.

I told him that we uncommingle the animals on Fridays, but that I have observed several rooms of monkeys who are not commingled when they are supposed to be. E said that someone previously told him to put in the computer that he had uncommingled the monkeys even though they were not commingled in the first place. When E questioned this, he was told just to enter the data like they were commingled even though this was untrue.

9/16/04

I spent the majority of today working on the start of study #6630-160 that I am running. This is a 13-week oral gavage study for a company [client's name]. S gave me this protocol several weeks ago and asked that I run it. Because I am not technically supposed to be running studies, S said that he would have to put me down as the "back-up" tech even though I will really be running the entire study as the head tech would. Even though I have finished my "mock" study and GLP training, I am supposed to be a backup tech several times before I actually run a study.

11/23/04

Today I helped dose the 7140-107 (client's name) board study. This compound is dosed IV, and as C was catheterizing the monkeys' legs, she had a very difficult time with one monkey. She stuck the monkey 3 times and then K stuck the monkey 3 times while trying to insert the catheter into her saphenous vein. I was called out of the room and did not get to see how many more times this poor monkey was stuck until they could give her the 10 minute IV dose. This same monkey looked horrible—she had alopecia all over her back and limbs and even her head. I commented about this to C and K but they would not even respond to me. I was recently told by one of the senior technicians that we are not supposed to enter an observation of "alopecia" unless all of the hair is gone. This is ridiculous as many of the monkeys lose their hair or hair-pluck and this is not entered into the computer only because all of the hair is not gone.

11/25/04

Today we had to dose the [client name] 7140-107 study. I went to do observations on some studies and then joined J in dosing the 7140-107 monkeys. J had 4 females tied up on the dosing boards and I began to help him. As K walked in, I caught a monkey and put her on the dosing board and told J her number was 22. K asked why we were dosing the females and told us that we were supposed to be dosing the males, not the females. J made a mistake and dosed the group 1 females (control) with the compound that was intended for the group 1 (control) males, and recorded this information on the paperwork as if he had correctly dosed the correct group 1 males whose numbers were written on the paperwork for the study. J told us that we should start dosing the group 2 males and forget about what happened with the group 1 females. Everyone agreed to follow what J had said.

The incidents described above demonstrate that Covance routinely falsifies records in an effort to conceal problems with the health of study animals, to cover up incompetence, and to circumvent shortages in personnel who have received the appropriate level of training.

VIII. COVANCE'S QUALITY ASSURANCE UNIT FAILS TO ENSURE THE INTEGRITY OF STUDIES AND CONFORMANCE WITH PROTOCOLS AND STANDARD OPERATING PROCEDURES, IN VIOLATION OF 21 C.F.R. § 58.35.

Of course, all of the incidents described in this letter, in addition to further incidents set forth in the USDA complaint, demonstrate a marked failure by Covance's Quality Assurance Unit in its duties to ensure the integrity of studies and compliance with protocols and standard operating procedures. This raises questions as to the competence of the personnel and the quality and frequency of inspections by the Quality Assurance Unit.

In conclusion, because of the chronic and serious nature of violations of the FDCA at Covance—violations that were committed by or sanctioned by senior personnel—it is imperative that the FDA investigate this matter thoroughly and take appropriate enforcement action. PETA's investigator is available to attest to the allegations set forth herein and to assist the agency in its investigation in any manner.

Thank you for your prompt attention to this matter. I can be reached at 757-962-8329.

Sincerely,



Lori Kettler
Counsel
Research & Investigations Department