FINAL SHOWN

Koch, Michael 01-11-2019

Total Time 00:15:35
Q. I want to start off with a little bit of background of yourself. What is your educational background?
A. So would you like me to start at my bachelor's degree, or would you like for me to start with my most recent education?
Q. Well, I think you should start off where you think it's relevant for your job today.
A. Okay. So I have a PhD from the University of Iowa. That was granted in 2005, in pharmacology. My professional experience since that time has been in regulatory toxicology. I've worked for Research in Ashland, Ohio, conducting regulatory toxicology studies from 2006 to 2008, and then from 2008 to 2010 I worked for Seventh Wave Labs, which is another contract research organization which does short-term toxicology work and pharmacokinetics. And then I joined Monsanto in 2010, and I'm -- well, I'm part of Bayer now, since
Q. Those various contract laboratories that you worked for prior to joining Monsanto, were -- did they do work for Monsanto?
A. Yes. The Research in Ashland, Ohio, did work for Monsanto. I don't recall working on any Monsanto studies there.
Q. So it would be fair to say then in your job as product safety center lead, you helped navigate and shape a complex international regulatory environment and helped gain regulatory approvals and freedom to operate?
A. There are many different regulatory paradigms around the world, and that's why it's a complex one, so yes, that is an accurate reflection.
Q. And so the product safety center lead -- part of your job was to ensure freedom to operate for the company's products?
A. As a part of engaging stakeholders, as -- part of that is sharing that data and communicating
43:23 with them, yeah.
43:24 Q. It says to accomplish this, the product
44:1 safety center lead must identify strategic challenges
44:2 to the development of new products and the defense of
44:3 existing products. Did I read that right?
44:4 A. Yes.
44:5 Q. What do you mean by the defense of
44:6 existing products?
44:7 A. So occasionally there are results
44:8 published in the public literature which are not --
44:9 which we feel are not accurate, and we take steps to
44:10 investigate whether or not they're accurate.

57:7 - 57:10 Koch, Michael 01-11-2019 (00:00:12)
57:7 Q. And is it true that Monsanto has developed
57:8 a group of third-party toxicologists who come to defend
57:9 Monsanto's products in the public domain specifically
57:10 as it relates to glyphosate?

57:12 - 57:17 Koch, Michael 01-11-2019 (00:00:21)
57:12 A. Monsanto contracts with independent
57:13 experts for their time and to provide their independent
57:14 opinions on our products.
57:15 Q. (By Mr. Wisner) So that's a yes? There's
57:16 a network of third-party toxicologists that Monsanto
57:17 pays for their time in defending glyphosate publicly?

57:20 - 57:21 Koch, Michael 01-11-2019 (00:00:03)
57:20 A. We pay them for their time and they
57:21 provide their independent opinions.

163:15 - 163:16 Koch, Michael 01-11-2019 (00:00:03)
163:15 Q. (By Mr. Wisner) How long does it take to
163:16 do a long-term animal carcinogenicity study?

163:20 - 164:11 Koch, Michael 01-11-2019 (00:00:39)
163:20 A. Carcinogenicity studies in mice typically
163:21 take 18 months and in rats two years.
163:22 Q. (By Mr. Wisner) And then it takes about,
163:23 what, another year or so to do all the histopathology
163:24 on those animals?
164:1 A. Yes, that's the dosing period for each of
164:2 those studies, and then there's the reporting process.
164:3 Yeah.
164:4 Q. So ballpark, to do a long-term rodent
164:5 carcinogenicity study it's approximately three years?
164:6 A. That's correct.
164:7 Q. So if Monsanto had started a long-term
164:8 animal carcinogenicity study in 2009, by the time you
164:9 arrived at Monsanto, and even today, we'd have data
164:10 about whether or not the formulated product induces
164:11 tumors; correct?
164:16 A. To my knowledge, Monsanto hasn't -- didn't
164:17 start a study in 2009 on the formulation, and so there
164:18 would be nothing to report.

205:18 Q. (By Mr. Wisner) Are you familiar with
205:19 ghostwriting?
205:21 A. It's a term that's out there.
205:22 Q. (By Mr. Wisner) And it's an unethical
205:23 thing to do; right?
206:1 A. There's a wide variety of things that
206:2 might fit the definition of ghostwriting.
206:3 Q. (By Mr. Wisner) So I'm sorry. What's the
206:4 answer to my question? Is ghostwriting unethical, sir?
206:5 It seems like a pretty straightforward question.
206:7 A. So as I said, there's a wide definition of
206:8 what people might call ghostwriting.
206:9 Q. (By Mr. Wisner) So you --
206:10 A. And it's hard to say what would be
206:11 unethical or not.
206:12 Q. So it's your testimony to this jury that
206:13 you can't say one way or the other whether ghostwriting
206:14 is just across the board unethical?
206:17 A. Yeah, I think it's -- I think that the
206:18 fact that multiple definitions of ghostwriting exist,
206:19 and so therefore it's hard to say whether or not it's
206:20 entirely inappropriate.
207:1 Q. When is ghostwriting appropriate, sir?
207:2 A. I think the term -- as I said, I think the
207:3 term means many things. Someone might use it as
207:4 shorthand for providing background information or
207:5 references or other things to facilitate someone else
207:6 writing a paper. I don't see anything wrong with that.
207:7 Ghostwriting could also be someone writing a paper and
207:8 someone else signing their name to it as them having
207:9 written it, and I would say that is probably -- that's
207:10 not appropriate.
207:11 Q. So that second one where someone else
207:12 writes it and then someone signs their name, so to
207:13 speak -- that's the unethical type?
207:14 A. I would not be comfortable doing that.
207:15 Q. And you wouldn't be comfortable for any of
207:16 the people that you work with or work under you doing
207:17 that; correct?
207:18 A. That's correct.

212:1 Q. (By Mr. Wisner) Isn't the actual truth of
212:2 the matter, sir, that the reason why Monsanto hasn't
212:3 done these long-term studies is because it would create
212:4 a dangerous precedent to be avoided?
212:5 A. No.

221:22 Q. Now, you've repeatedly
221:23 stated that studies were not needed to study the
221:24 formulated product of Roundup; correct?
221:25 A. I've stated that carcinogenicity studies
221:26 aren't necessary with the formulated product, yes.
221:27 Q. However, Dr. Farmer in 2003 openly
221:28 admitted that Monsanto could not state that Roundup is
221:29 not carcinogenic because they had not done carcinogenic
221:30 studies on Roundup; correct?

222:9 A. I don't know what Donna meant when she
222:10 wrote that.
222:11 Q. (By Mr. Wisner) But she wrote it; right?
222:12 A. That's what's in the e-mail.
222:13 Q. She wrote the same thing in 2009, six
222:14 years later; correct?
A. Okay. 2009 e-mail says you cannot say that Roundup does not cause cancer. I don't know what she meant by that.

Q. (By Mr. Wisner) Well, finish the sentence.

A. We have not done carcinogenicity studies with Roundup.

Q. So she meant based on what she wrote that you can't say it doesn't cause cancer because we haven't done cancer studies on Roundup?

A. I don't know what she intended when she wrote that. I wasn't there.

Q. Let's start with your background. Where do you live now?

A. I live in the suburbs of St. Louis.

Q. And how long have you lived there?

A. I've lived there for about ten years.

Q. Are you married?

A. I am married and I have two children and two dogs.

Q. Do you use Roundup?

A. I do.

Q. How do you use it?

A. I have a deck under my house which has rocks spread out and weeds will grow up underneath it. I spray it on the weeds that are under my deck.

Q. (By Mr. Brenza) Do you use any sort of protective gear when you're spraying?

A. Typically.

Q. Let's talk a little bit about your education. Where did you get your undergraduate degree?
A. I did -- I have a bachelor's in science and biology from Maryville University in St. Louis.

Q. And where did you get your PhD?

A. From the University of Iowa.

Q. After you got done working at -- earning your PhD, where'd you first work?

A. My first role was at WIL Research in Ashland, Ohio -- it's not part of the Charles River system of labs, but they're still located in Ashland -- doing regulatory toxicology studies in mice, rats, guinea pigs, dogs, nonhuman primate -- nonhuman primates.

Q. Did any of your work there have anything to do with glyphosate?

A. It did not.

Q. What kind of regulatory -- when you say regulatory toxicology, what is that?

A. Regulatory toxicology is a field of toxicology that generates data according to international guidelines, and we've mentioned the OECD test guidelines previously, and those are internationally agreed-upon guidelines of how to conduct a certain type of study, whether it's a carcinogenicity study, a genotoxicity study, an acute oral toxicity study. All those types of studies and more have international guidelines on how to conduct a study.

Q. What's the benefit of using OECD standards for your regulatory toxicology?

A. So the endpoints in OECD studies are known to be accurate predictors of toxicity, whereas investigative science, they may have -- they may detect a difference, but its relevance to toxicity is unknown.

Q. Does -- do regulatory bodies accept toxicology that doesn't comply with international standards?

A. No, the test guidelines are international standards and then there are typically national standards to which they're harmonized. For example, the EPA expects that studies be conducted in accordance
with OECD test guidelines and also any guidance that they have issued as well on that type of study. Q. And in your practice both at Monsanto and before, have you made an effort to adhere to good lab practices and international lab guidelines? A. Yeah, the good lab practices are sort of a cook book for how to make a study reproducible. They ensure that accurate records are kept on what was done, and should the study need to be repeated, you would know exactly how to do it. The OECD test guidelines likewise ensure quality by making minimal suggestions of animal number and the endpoints to include. Q. Are those both good lab practices and international study guidelines -- are those things that you've endeavored to abide by when you've conducted or overseen research?

A. Yes.

Q. Exhibit 11. Exhibit 11 is an e-mail dated September 21, 2009, from Donna Farmer -- A. Yes.

Q. -- involving Roundup. Do you see that?

A. I do.

Q. Before you came to your deposition today, had you ever seen Exhibit 11?

A. No.

Q. Had you ever discussed Exhibit 11 with anyone?

A. No.

Q. And when you were answering questions about Exhibit 11 today, did you have any personal knowledge about it?

A. No.

Q. And I believe you mentioned a number of times during your testimony that there was another body of knowledge, the regulatory data, that accompanies products like glyphosate that are heavily regulated. Is that right?

A. Yes, that's correct. I made reference to
the regulatory dataset for glyphosate because it's an unusually large dataset. It has both the Monsanto safety data as well as safety data from other registrants of glyphosate. Since glyphosate went off patent, many other chemical manufacturers have begun manufacturing glyphosate as well, and they've generated safety data in addition to what Monsanto has, so it has a larger safety dataset than usual.

Q. What kind of data is in the regulatory safety data?

A. So there's an extensive toxicology database. There's acute, there's repeat dose, there's developmental and reproductive toxicology, there's genotoxicity, there's carcinogenicity, and quite a few other studies. In addition to human safety studies, there's ecotox studies, residue studies, and just a considerable amount of data.

Q. And that's all generated for each registrant that wants to be allowed to make glyphosate?

A. So now that the joint -- the glyphosate task force has been formed they're sharing data, but that is a pool of data from which members can pull from.

Q. Do you know when Monsanto first pulled together a package of all of this information and provided it to a regulatory body?

A. I don't.

Q. But glyphosate was first approved sometime in 1975; is that right?

A. Yeah, I know that glyphosate was originally approved by regulatory authorities in the 1970s and has been reapproved since then, in the U.S., Canada, Europe, in Japan, and Australia. So it's been successfully registered and reregistered around the world based on the regulatory dataset.

Q. Do all of those entities that you've mentioned, those regulatory bodies in the different countries that have approved glyphosate -- do they all take the same data package and evaluate it?
Q. (By Mr. Brenza) If you know, I don't.
A. So yeah, I don't know all the data.
Q. Do -- and then you said it's been reregistered a number of times -- glyphosate?
A. Yes.
Q. Does -- when glyphosate is reregistered, does that require supplementing the regulatory database that's provided to the regulators?
A. When new data requirements evolve, we have to meet those data requirements, and so over time additional data has been generated as regulatory requirements have been put in place.
Q. If -- am I right that the regulatory data package needs to be submitted before a product is approved by the EPA?
A. Yes. Regulatory agencies expect to review the data. It takes us a couple years, maybe three, four years to typically generate a full dataset based on the timing of the studies and how they need to be run sequentially, and then the EPA conducts their review, which can take another two to three years.
Q. And so that would have happened at least for the first time before 1975, for glyphosate?
A. If the first approval was in 1975, I would imagine it was submitted well before that, but I don't know for a fact.
Q. Yeah. I mean, obviously you weren't there at the time, but you know that to get approval you have to submit this information?
A. Yes.

Koch, Michael 01-11-2019 (00:00:29)
Q. Based on the toxicology work you've done, do you have an understanding about whether glyphosate can be used safely?
A. So I'm not intimately familiar with the toxicology dataset for glyphosate, but I know people who are, and they're strongly convinced of the safety.
The fact that many regulatory agencies have reviewed that data and come to the same conclusions gives me pretty strong assurance that it is completely safe.