FINAL SHOWN

Koch, Michael 01-11-2019

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16:7 - 17:7	**Koch, Michael 01-11-2019 (00:01:23)**	MK2_COMBINED_06.1

16:7 Q. I want to start off with a little bit of
16:8 background of yourself. What is your educational
16:9 background?
16:10 A. So would you like me to start at my
16:11 bachelor's degree, or would you like for me to start
16:12 with my most recent education?
16:13 Q. Well, I think you should start off where
16:14 you think it's relevant for your job today.
16:15 A. Okay. So I have a PhD from the University
16:16 of Iowa. That was granted in 2005, in pharmacology.
16:17 My professional experience since that time has been in
16:18 regulatory toxicology. I've worked for Research in
16:19 Ashland, Ohio, conducting regulatory toxicology studies
16:20 from 2006 to 2008, and then from 2008 to 2010 I worked
16:21 for Seventh Wave Labs, which is another contract
16:22 research organization which does short-term toxicology
16:23 work and pharmacokinetics. And then I joined Monsanto
16:24 in 2010, and I'm -- well, I'm part of Bayer now, since
17:1 the acquisition.
17:2 Q. Those various contract laboratories that
17:3 you worked for prior to joining Monsanto, were -- did
17:4 they do work for Monsanto?
17:5 A. Yes. The -- Research in Ashland, Ohio,
17:6 did work for Monsanto. I don't recall working on any
17:7 Monsanto studies there.

43:10 - 44:10	**Koch, Michael 01-11-2019 (00:01:05)**	MK2_COMBINED_06.2

43:10 Q. So it would be fair to say then in your
43:11 job as product safety center lead, you helped navigate
43:12 and shape a complex international regulatory
43:13 environment and helped gain regulatory approvals and
43:14 freedom to operate?
43:15 A. There are many different regulatory
43:16 paradigms around the world, and that's why it's a
43:17 complex one, so yes, that is an accurate reflection.
43:18 Q. And so the product safety center lead --
43:19 part of your job was to ensure freedom to operate for
43:20 the company's products?
43:21 A. As a part of engaging stakeholders, as --
43:22 part of that is sharing that data and communicating

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	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?	MK2_COMBINED_06.3
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?	MK2_COMBINED_06.4
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.	MK2_COMBINED_06.5
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?	MK2_COMBINED_06.6
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	MK2_COMBINED_06.7

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	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 - 164:18	**Koch, Michael 01-11-2019 (00:00:08)** 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.	MK2_COMBINED_06.8
205:18 - 205:19	**Koch, Michael 01-11-2019 (00:00:02)** 205:18 Q. (By Mr. Wisner) Are you familiar with 205:19 ghostwriting?	MK2_COMBINED_06.9
205:21 - 205:23	**Koch, Michael 01-11-2019 (00:00:05)** 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?	MK2_COMBINED_06.10
206:1 - 206:5	**Koch, Michael 01-11-2019 (00:00:13)** 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.	MK2_COMBINED_06.11
206:7 - 206:14	**Koch, Michael 01-11-2019 (00:00:18)** 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?	MK2_COMBINED_06.12
206:17 - 206:20	**Koch, Michael 01-11-2019 (00:00:11)** 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.	MK2_COMBINED_06.13
207:1 - 207:18	**Koch, Michael 01-11-2019 (00:00:47)** 207:1 Q. When is ghostwriting appropriate, sir?	MK2_COMBINED_06.14

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	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 - 212:5	**Koch, Michael 01-11-2019 (00:00:14)** 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.	MK2_COMBINED_06.15
221:22 - 222:6	**Koch, Michael 01-11-2019 (00:00:22)** 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? 222:1 A. I've stated that carcinogenicity studies 222:2 aren't necessary with the formulated product, yes. 222:3 Q. However, Dr. Farmer in 2003 openly 222:4 admitted that Monsanto could not state that Roundup is 222:5 not carcinogenic because they had not done carcinogenic 222:6 studies on Roundup; correct?	MK2_COMBINED_06.20 EXHIBIT 426.1.7
222:9 - 222:14	**Koch, Michael 01-11-2019 (00:00:08)** 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?	MK2_COMBINED_06.21 EXHIBIT 245.1.5

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222:19 - 223:4	**Koch, Michael 01-11-2019 (00:00:21)** 222:19 A. Okay. 2009 e-mail says you cannot say 222:20 that Roundup does not cause cancer. I don't know what 222:21 she meant by that. 222:22 Q. (By Mr. Wisner) Well, finish the 222:23 sentence. 222:24 A. We have not done carcinogenicity studies 223:1 with Roundup. 223:2 Q. So she meant based on what she wrote that 223:3 you can't say it doesn't cause cancer because we 223:4 haven't done cancer studies on Roundup?	MK2_COMBINED_06.22
223:7 - 223:8	**Koch, Michael 01-11-2019 (00:00:03)** 223:7 A. I don't know what she intended when she 223:8 wrote that. I wasn't there.	MK2_COMBINED_06.23
357:11 - 357:21	**Koch, Michael 01-11-2019 (00:00:20)** 357:11 Q. Let's start with your background. Where 357:12 do you live now? 357:13 A. I live in the suburbs of St. Louis. 357:14 Q. And how long have you lived there? 357:15 A. I've lived there for about ten years. 357:16 Q. Are you married? 357:17 A. I am married and I have two children and 357:18 two dogs. 357:19 Q. Do you use Roundup? 357:20 A. I do. 357:21 Q. How do you use it?	MK2_COMBINED_06.25 clear
357:23 - 360:20	**Koch, Michael 01-11-2019 (00:03:37)** 357:23 A. I have a deck under my house which has 357:24 rocks spread out and weeds will grow up underneath it. 358:1 I spray it on the weeds that are under my deck. 358:2 Q. (By Mr. Brenza) Do you use any sort of 358:3 protective gear when you're spraying? 358:4 A. Just typically the clothes I'm wearing. 358:5 Sometimes gardening gloves. 358:6 Q. Do you wear the gardening gloves because 358:7 you already have them on? 358:8 A. Typically. 358:9 Q. Let's talk a little bit about your 358:10 education. Where did you get your undergraduate 358:11 degree?	MK2_COMBINED_06.26

358:12 A. I did -- I have a bachelor's in science
358:13 and biology from Maryville University in St. Louis.
358:14 Q. And where did you get your PhD?
358:15 A. From the University of Iowa.
358:16 Q. After you got done working at -- earning
358:17 your PhD, where'd you first work?
358:18 A. My first role was at WIL Research in
358:19 Ashland, Ohio -- it's not part of the Charles River
358:20 system of labs, but they're still located in Ashland --
358:21 doing regulatory toxicology studies in mice, rats,
358:22 guinea pigs, dogs, nonhuman primate -- nonhuman
358:23 primates.
358:24 Q. Did any of your work there have anything
359:1 to do with glyphosate?
359:2 A. It did not.
359:3 Q. What kind of regulatory -- when you say
359:4 regulatory toxicology, what is that?
359:5 A. Regulatory toxicology is a field of
359:6 toxicology that generates data according to
359:7 international guidelines, and we've mentioned the OECD
359:8 test guidelines previously, and those are
359:9 internationally agreed-upon guidelines of how to
359:10 conduct a certain type of study, whether it's a
359:11 carcinogenicity study, a genotoxicity study, an acute
359:12 oral toxicity study. All those types of studies and
359:13 more have international guidelines on how to conduct a
359:14 study.
359:15 Q. What's the benefit of using OECD standards
359:16 for your regulatory toxicology?
359:17 A. So the endpoints in OECD studies are known
359:18 to be accurate predictors of toxicity, whereas
359:19 investigative science, they may have -- they may detect
359:20 a difference, but its relevance to toxicity is unknown.
359:21 Q. Does -- do regulatory bodies accept
359:22 toxicology that doesn't comply with international
359:23 standards?
359:24 A. No, the test guidelines are international
360:1 standards and then there are typically national
360:2 standards to which they're harmonized. For example,
360:3 the EPA expects that studies be conducted in accordance

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	360:4 with OECD test guidelines and also any guidance that 360:5 they have issued as well on that type of study. 360:6 Q. And in your practice both at Monsanto and 360:7 before, have you made an effort to adhere to good lab 360:8 practices and international lab guidelines? 360:9 A. Yeah, the good lab practices are sort of a 360:10 cook book for how to make a study reproducible. They 360:11 ensure that accurate records are kept on what was done, 360:12 and should the study need to be repeated, you would 360:13 know exactly how to do it. The OECD test guidelines 360:14 likewise ensure quality by making minimal suggestions 360:15 of animal number and the endpoints to include. 360:16 Q. Are those both good lab practices and 360:17 international study guidelines -- are those things that 360:18 you've endeavored to abide by when you've conducted or 360:19 overseen research? 360:20 A. Yes.	
370:23 - 371:13	**Koch, Michael 01-11-2019 (00:00:28)** 370:23 Q. Exhibit 11. Exhibit 11 is an e-mail dated 370:24 September 21, 2009, from Donna Farmer -- 371:1 A. Yes. 371:2 Q. -- involving Roundup. Do you see that? 371:3 A. I do. 371:4 Q. Before you came to your deposition today, 371:5 had you ever seen Exhibit 11? 371:6 A. No. 371:7 Q. Had you ever discussed Exhibit 11 with 371:8 anyone? 371:9 A. No. 371:10 Q. And when you were answering questions 371:11 about Exhibit 11 today, did you have any personal 371:12 knowledge about it? 371:13 A. No.	MK2_COMBINED_06.27 EXHIBIT 245.1.2
372:17 - 374:13	**Koch, Michael 01-11-2019 (00:02:24)** 372:17 Q. And I believe you mentioned a number of 372:18 times during your testimony that there was another body 372:19 of knowledge, the regulatory data, that accompanies 372:20 products like glyphosate that are heavily regulated. 372:21 Is that right? 372:22 A. Yes, that's correct. I made reference to	MK2_COMBINED_06.28 clear

372:23 the regulatory dataset for glyphosate because it's an
372:24 unusually large dataset. It has both the Monsanto
373:1 safety data as well as safety data from other
373:2 registrants of glyphosate. Since glyphosate went off
373:3 patent, many other chemical manufacturers have begun
373:4 manufacturing glyphosate as well, and they've generated
373:5 safety data in addition to what Monsanto has, so it has
373:6 a larger safety dataset than usual.
373:7 Q. What kind of data is in the regulatory
373:8 safety data?
373:9 A. So there's an extensive toxicology
373:10 database. There's acute, there's repeat dose, there's
373:11 developmental and reproductive toxicology, there's
373:12 genotoxicity, there's carcinogenicity, and quite a few
373:13 other studies. In addition to human safety studies,
373:14 there's ecotox studies, residue studies, and just a
373:15 considerable amount of data.
373:16 Q. And that's all generated for each
373:17 registrant that wants to be allowed to make glyphosate?
373:18 A. So now that the joint -- the glyphosate
373:19 task force has been formed they're sharing data, but
373:20 that is a pool of data from which members can pull
373:21 from.
373:22 Q. Do you know when Monsanto first pulled
373:23 together a package of all of this information and
373:24 provided it to a regulatory body?
374:1 A. I don't.
374:2 Q. But glyphosate was first approved sometime
374:3 in 1975; is that right?
374:4 A. Yeah, I know that glyphosate was
374:5 originally approved by regulatory authorities in the
374:6 1970s and has been reapproved since then, in the U.S.,
374:7 in Canada, in Europe, in Japan, and Australia. So it's
374:8 been successfully registered and reregistered around
374:9 the world based on the regulatory dataset.
374:10 Q. Do all of those entities that you've
374:11 mentioned, those regulatory bodies in the different
374:12 countries that have approved glyphosate -- do they all
374:13 take the same data package and evaluate it?

374:15 - 375:23 **Koch, Michael 01-11-2019 (00:01:28)**

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374:15 Q. (By Mr. Brenza) If you know. I don't
374:16 want to --
374:17 A. So yeah, I don't know all the data
374:18 requirements internationally. I know that typically
374:19 the EU has more data requirements.
374:20 Q. Do -- and then you said it's been
374:21 reregistered a number of times -- glyphosate?
374:22 A. Yes.
374:23 Q. Does -- when glyphosate is reregistered,
374:24 does that require supplementing the regulatory database
375:1 that's provided to the regulators?
375:2 A. When new data requirements evolve, we have
375:3 to meet those data requirements, and so over time
375:4 additional data has been generated as regulatory
375:5 requirements have been put in place.
375:6 Q. If -- am I right that the regulatory data
375:7 package needs to be submitted before a product is
375:8 approved by the EPA?
375:9 A. Yes. Regulatory agencies expect to review
375:10 the data. It takes us a couple years, maybe three,
375:11 four years to typically generate a full dataset based
375:12 on the timing of the studies and how they need to be
375:13 run sequentially, and then the EPA conducts their
375:14 review, which can take another two to three years.
375:15 Q. And so that would have happened at least
375:16 for the first time before 1975, for glyphosate?
375:17 A. If the first approval was in 1975, I would
375:18 imagine it was submitted well before that, but I don't
375:19 know for a fact.
375:20 Q. Yeah. I mean, obviously you weren't there
375:21 at the time, but you know that to get approval you have
375:22 to submit this information?
375:23 A. Yes.

389:15 - 389:23 **Koch, Michael 01-11-2019 (00:00:29)** MK2_COMBINED_06.30

389:15 Q. Based on the toxicology work you've done,
389:16 do you have an understanding about whether glyphosate
389:17 can be used safely?
389:18 A. So I'm not intimately familiar with the
389:19 toxicology dataset for glyphosate, but I know people
389:20 who are, and they're strongly convinced of the safety.

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389:21 The fact that many regulatory agencies have reviewed
389:22 that data and come to the same conclusions gives me
389:23 pretty strong assurance that it is completely safe.

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Documents Shown
EXHIBIT 245
EXHIBIT 426