

1 Two of the other cases were very, very complicated  
2 -- the lady with multiple adhesions. So, I think we should  
3 not be counting all these patients indiscriminately as  
4 complications of constipation.

5 DR. HANAUER: Thank you. Yes, Dr. Siegel?

6 DR. SIEGEL: I don't know if I am getting this  
7 point correctly, but to me, I don't think it matters too  
8 much whether all of those patients were specifically related  
9 to the drug in a causal factor. I think that, especially  
10 once it becomes a little bit looser in terms of the  
11 prescribing, it is important to have some sort of a  
12 benchmark so that we can see that when patients who aren't  
13 necessarily the perfect patients for these drugs are  
14 receiving it, whether we can see, you know, how constipation  
15 and those serious complications change when those kind of  
16 practice patterns are established.

17 DR. HANAUER: Yes?

18 MR. HAMMES: Obviously, the rate of serious  
19 complications that we are seeing enough were enough to set  
20 off some flags. I would like to think that the efforts of  
21 today are going to decrease that rate. So, I would say  
22 let's start where we are and monitor it, and if it goes up  
23 from here we have a real problem, and it should go down.

24 DR. HANAUER: Any other goals that the committee  
25 would like to address?

1 DR. KENT: I have a question.

2 DR. HANAUER: Yes?

3 DR. KENT: That leads into something you said  
4 before that I think is very important. You made the comment  
5 before, Dr. Hanauer, that the FDA shouldn't be practicing  
6 medicine, and the risk-benefit should be judged in patients  
7 for whom the drug is indicated. So, if we are getting  
8 complications of constipation because someone with a  
9 stricture is put on the drug, what does that mean? What is  
10 your view of what that means for the drug?

11 DR. HANAUER: Well, that means that my view of the  
12 risk management is that we have to compare the risk to  
13 patients in whom it is indicated compared to those who have  
14 complications outside of it. That was the point that I  
15 personally made to the agency before.

16 DR. KENT: But what is the rate we are trying to  
17 decrease?

18 DR. HANAUER: Of complications. Well, we saw some  
19 of the complications in clinical trials and we saw some  
20 outside of them. So, I think that your question is what we  
21 are all grappling with.

22 DR. KENT: Okay. Just one comment, very brief, on  
23 ischemic colitis, and that is the whole discussion and the  
24 whole aura around ischemic colitis is as if it is an  
25 extremely rare event and this is very unusual. But what the

1 data are beginning to show is that ischemic colitis actually  
2 occurs relatively frequently. We have a huge program of  
3 epidemiologic studies to try and get that rate, and it is  
4 not 100 percent sure that Lotronex is actually causing all  
5 of these cases, but we do take your comments.

6 DR. HANAUER: We understand that.

7 DR. LAINE: There were zero in the placebo group.  
8 So.

9 DR. GURWITZ: I think it is challenging to  
10 stipulate benchmarks without knowing the prevalence of the  
11 condition in the population and the level of use, and 1/1000  
12 may be acceptable under some circumstances but if used among  
13 millions of people, then it is potentially unacceptable, and  
14 unless we know that, that is an issue.

15 DR. WEISS: I want to take some disagreement with  
16 the fact that we should only look at those who are properly  
17 prescribed the drug in the risk-benefit equation. I think  
18 we have to look at all the people that are prescribed the  
19 drug whether or not it is for the indication when we think  
20 about the risk-benefits.

21 DR. KRAMER: I want to second that. That, in  
22 essence, is a reformation of what I said a little bit  
23 earlier. In my opinion, if the overwhelming majority of  
24 people who get the drug get it inappropriately because of a  
25 misdiagnosis, or whatever, and therefore, the overwhelming

1 majority of consequences is in people who didn't need to be  
2 on the drug in the first place, that represents a failure of  
3 risk management. I think we ought to take a look at it as  
4 risk management, not just what happens in people who have a  
5 perfectly accurate diagnosis and have a complication.

6 DR. WELTON: Especially in a disease process that  
7 is so hard to really diagnose.

8 DR. HANAUER: Thank you.

9 DR. AVORN: I have another goal of risk  
10 management, in response to you question, and that is that I  
11 want to come back to the concept of risk in the absence of  
12 benefit. I wonder whether there ought to be a way of  
13 thinking about the labeling that would encourage doctors to  
14 reassess patients after ten weeks of therapy and  
15 systematically study whether or not the patient is  
16 benefiting, perhaps by a temporary cessation of therapy, and  
17 see if the patient continues as well as they were or  
18 deteriorates. I think that is a small price to pay for the  
19 possibility of getting a lot of patients who may not be  
20 benefiting from the drug off the drug. I realize that is  
21 not Glaxo's favorite concept, but in terms of not wanting to  
22 expose people to any risk if they are not getting a benefit,  
23 perhaps there ought to be a protocol that is recommended  
24 after twelve weeks, which after all is the main amount of  
25 time for which there is data, saying there ought to be a

1 drug holiday and reassess X weeks after that.

2 DR. HANAUER: Along those lines, yesterday we  
3 recommended a maintenance trial for another drug. You guys  
4 have a maintenance trial going on, a longer than three-month  
5 trial?

6 DR. MANGEL: We have a 12-month efficacy study of  
7 which we will have the results at the end of July.

8 DR. HANAUER: Thank you. Dr. Welton?

9 DR. WELTON: The problem with the drug holiday --  
10 correct me if I am wrong, but I thought your graph showed  
11 that the patients all had return of their symptoms with  
12 withdrawal of placebo and drug.

13 DR. AVORN: That was average; it wasn't all.

14 DR. WELTON: Average, okay.

15 DR. HANAUER: Any other goals for risk management  
16 that we would like to inform the agency of?

17 DR. HOUN: I have a question on death in terms of  
18 a goal.

19 DR. HANAUER: Death? That is not a goal.

20 [Laughter]

21 Should we be looking at deaths?

22 DR. LAINE: You should always look at death. It  
23 is obviously the most objective outcome. I would obviously  
24 look at it, I am not sure that I would include it. The  
25 likelihood of showing difference in death, it seems to me,

1 at this time, even in the studies mentioned, is extremely  
2 small.

3 DR. HANAUER: We are not worried about dying in a  
4 composite.

5 DR. BLUM: Unless it is something to do with bowel  
6 disease -- a perforation etc., something of that nature.

7 DR. HOUN: That is what the question was in terms  
8 of the complications now show, you know, colectomy, toxic  
9 megacolon, perforation. In the future, it is reasonable to  
10 assume there will be a death report or more coming in, and I  
11 wanted to just make sure that that was discussed here so  
12 that when that report does come in the future we have some  
13 of your guidance.

14 DR. HANAUER: I think we are going to have to see  
15 the deaths within the context. If we see death of a 20-year  
16 old with diarrhea predominant irritable bowel from an  
17 ischemic event that didn't have any other predisposing  
18 factors, versus a 75-year old with diverticulitis who has a  
19 diverticular abscess, it is going to impact us differently.

20 DR. WELTON: You are more likely to see it with  
21 the constipation patient, not with the ischemic colitis  
22 patient.

23 DR. WEISS: But I definitely think you need to  
24 monitor the complications and the outcomes of the people  
25 that do have those conditions because I think that is going

1 to be very important.

2 DR. HANAUER: That is the next question. The drug  
3 was released in February. When is the next time point when  
4 the agency should be looking at that? The company tells us  
5 that they should have some data by the end of this year  
6 regarding some of their trials. Is that satisfactory? Do  
7 we need it sooner? Later? We are happy with the end of  
8 this year.

9 Anything else, Dr. Houn, on that first category?  
10 We can move on? Okay, now we are talking about what  
11 interventions in the risk management program should be  
12 undertaken regarding Lotronex. Please discuss which risk  
13 management tools should be used to reduce the risk and to  
14 achieve the desired goals and outcomes. As outlined,  
15 various tools -- we have discussed today various potential  
16 tools that are not limited to but include changes in the  
17 product labeling including boxed warnings, special education  
18 programs, the potential of a medication guide, and the  
19 epidemiologic studies that have been discussed by the  
20 sponsor, and potential studies that could also be done by  
21 the agency, and limiting distribution of Lotronex to certain  
22 patients or physicians.

23 I think what we will do is take these one at a  
24 time for discussion. The first, since it is probably the  
25 most important to everybody, is the issue of labeling and

1 whether boxed warnings are necessary at this point. We have  
2 heard from the sponsor, for a variety of reasons, that they  
3 don't think it is necessary but certainly now it is time for  
4 the committee to discuss whether the committee feels a boxed  
5 warning is necessary. Let's hear discussions regarding  
6 that. Dr. Wolfe, you already preceded this with comments.  
7 Do you have anything further to add about a box?

8 DR. WOLFE: I do have one comment. Again, I am  
9 not advocating it necessarily, I am just saying it is  
10 written down as a consideration. The other aspect that was  
11 mentioned I really disagree with is looking at past drugs.  
12 Past performance is not necessarily an indication of what we  
13 should do in the future. We had a drug recently that didn't  
14 have a proper warning and obviously everyone wants to  
15 prevent that from occurring again. I don't think anybody  
16 disagrees that some kind of warning is necessary to make  
17 sure this doesn't actually become a problem.

18 DR. HANAUER: The other options along the labeling  
19 that we have heard are increased warnings or highlighting of  
20 the warnings, etc. Dr. Kramer, do you have a comment?

21 DR. KRAMER: Well, I will tell you why I lean  
22 toward a boxed warning. I learned quite a bit this morning.  
23 One of the things I learned from listening to the very  
24 poignant stories who suffer with the problem is that there  
25 is a sense that even their physicians don't have all the



1 appropriate information to really help them benefit but also  
2 prevent their suffering from the treatment itself. So, I am  
3 looking for multiple avenues to educate both the sufferer  
4 and the physician who is trying to help them, and one of the  
5 primary avenues that hasn't been pursued yet is the boxed  
6 warning.

7 That is the reason I asked specifically this  
8 morning what is the downside, in terms of educating the  
9 professional public, to having a boxed warning. Although I  
10 recognize it is not an attractive thing to a pharmaceutical  
11 company, I didn't hear a specific downside as part of an  
12 educational program.

13 DR. HANAUER: I am going to bring the boxed  
14 warning to a vote unless there is any other discussion  
15 around it. I presume that you guys want an opinion on  
16 labeling issues.

17 DR. HOUN: Well, this committee is not really  
18 charged with voting because most of the people are guests  
19 here. So, what we wanted to have was a brainstorming  
20 session, and I suggest that if you did want people to talk  
21 about advantages or disadvantages of boxed and you want to  
22 bring out people who haven't said things, you can do that.

23 DR. HANAUER: So, we don't have to vote on any of  
24 this?

25 DR. HOUN: You don't have to vote.

1 DR. HANAUER: Do you want us to? Do you want a  
2 sense of the committee?

3 DR. HOUN: A sense is fine.

4 DR. HAVLIK: I was impressed, actually, that the  
5 company had at least gone half the way to a box because, if  
6 I interpreted their revision of the labeling, they have it  
7 in bold as number one warning that constipation is the thing  
8 to worry about. I am not in practice so it is easy for me  
9 what I think I would do, but that would certainly get my  
10 attention.

11 From the drug company's side, it would seem right  
12 now that as much preventive medicine that could be exercised  
13 that would not undercut the ability to promote the drug is  
14 to the company's advantage. So, I am kind of caught between  
15 saying that what I see in the labeling is pretty good versus  
16 not really now knowing whether the physicians are going to  
17 respond adequately to that. In fact, I had a discussion  
18 with a practicing internist who gets bombarded. I won't  
19 speak for him but I had the feeling like even a warning  
20 might not be enough to get his attention.

21 DR. HANAUER: Well, let's take it right to the  
22 proposed labeling and asked for discussions off of that.

23 DR. HOMBOE: I just want to comment briefly. I am  
24 the general internist being referred to, but if you look at  
25 the data -- and I think we also heard some this morning, the

1 printed materials, whether it be a box or a "dear healthcare  
2 provider" letter, don't necessarily work very well. We have  
3 seen that in other areas of medicine, including guidelines  
4 which are not followed. So, regardless whether you use the  
5 black box, I think at a minimum you are going to have to  
6 highlight the things you are most concerned about, whether  
7 it be a black box, medication guide etc., but you are going  
8 to have to take it another step. I honestly don't believe  
9 that publishing the stuff and putting it in as inserts is  
10 going to be enough. I think it is really going to have to  
11 be part of the education program that has been talked about.

12 DR. HANAUER: Well, we agree. We have heard that  
13 irritable bowel is a multi-component disease and that risk  
14 management is a multi-component attempt at solution, and  
15 everything we are going to talk about is assuming other  
16 things.

17 DR. WOLFE: One point that was alluded to before  
18 was the role of the drug rep. I think you have a program in  
19 place, and I think that is very laudable and very important  
20 because a lot of physicians get their information from the  
21 rep. They have to pass a test to make sure they know --  
22 they have to really tell physicians to prescribe this drug  
23 appropriately.

24 DR. HANAUER: Let's just go to the label and get  
25 some comments on this. Indications and usages -- is this

1 okay, or do you want to modify it or what do you want to do?

2 DR. HOUN: It is fine to get suggestions.

3 DR. HANAUER: You are not thrilled with it.

4 DR. HOUN: The concepts. Don't edit the words,  
5 but the concepts.

6 DR. HANAUER: Got that charge? So, the  
7 indications -- Lotronex is indicated for the treatment of  
8 women --

9 DR. LAINE: Where are we?

10 DR. HANAUER: We are on page five of the draft.  
11 Lotronex is indicated for the treatment of women with  
12 diarrhea-predominant irritable bowel syndrome. Diarrhea-  
13 predominant IBS is characterized by at least three months of  
14 recurrent or continuous symptoms of abdominal pain or  
15 discomfort and diarrhea with either urgency and/or an  
16 increase in frequency. See appendix, and the appendix  
17 describes the wrong criteria that support diagnosis of  
18 diarrhea-predominant irritable bowel syndrome, abnormal  
19 stool frequency, greater than three bowel movements per day;  
20 abnormal stool form, loose or watery; and abnormal stool  
21 passage, urgency or feeling of incomplete evacuation. So,  
22 without talking about the words --

23 DR. LAINE: It is interesting because the  
24 indications say three months of basically pain and diarrhea.  
25 You know, diagnostic criteria talk about any 12 weeks within

1 the last one year. I am not saying that they are absolutely  
2 exclusive but one is stronger, if you will, in terms of  
3 talking about diarrhea predominant right in the recent past,  
4 while the other one could be read as six months ago, you  
5 know, somebody had diarrhea and it is resolved now.

6 DR. KENT: We put it as it is because we felt it  
7 was stronger the way it is.

8 DR. LAINE: I like it better in the indications is  
9 what I am saying.

10 DR. HANAUER: The next are the contraindications,  
11 which are patients with a history of chronic or severe  
12 constipation or sequelae from constipation; history of  
13 intestinal obstruction and/or stricture, toxic megacolon,  
14 perforation or adhesions; a history of ischemic colitis; or  
15 known hypersensitivity. In addition, should not be  
16 initiated in patients experiencing constipation which they  
17 describe as less than three bowel movements per week, and/or  
18 hard or lumpy stools and/or straining during a bowel  
19 movement.

20 DR. LAINE: Now we are in the recent past, for  
21 instance -- in other words, those who had it three weeks  
22 ago, I wouldn't include them, as an example, something along  
23 those lines.

24 DR. WOLFE: What about alternators, people who  
25 have constipation alternating with diarrhea?

1 DR. HANAUER: Is that a contraindication? Is  
2 alternating diarrhea and constipation a contraindication?

3 DR. LAINE: What I was trying to say is if they  
4 had constipation fairly recently it would be, but if they  
5 had it six or eight months ago -- I mean, I am making broad  
6 statements, but if they had it a couple of weeks ago, it  
7 would be; if they had it months and months ago, it wouldn't  
8 be. Again, I am not sure that is based on great evidence  
9 but that is what I would maybe suggest to handle that a  
10 little.

11 MR. LEVIN: Is there another way to deal with  
12 that? Going back to the indications and usage, we said the  
13 safety and effective has not been established in men.  
14 Should something be said -- the safety and effective has not  
15 been established for alternating diarrhea? I don't know why  
16 we just pick men. What about all the other conditions?

17 DR. HANAUER: I think that is a very good point.  
18 Thank you. Warnings -- gee, I really don't want to read  
19 this whole thing. It is on the bottom of page six --

20 DR. SURAWICZ: We have read it; it is good.

21 DR. RACZKOWSKI: Dr. Hanauer, one of the issues  
22 that has come up in the contraindications section is the  
23 notion of severe constipation as opposed to mild and  
24 moderate constipation, and the definition of severe  
25 constipation being a subjective one. I wonder if the

1 committee could just give some input about their comfort  
2 level with use of that sort of terminology. Is it specific  
3 enough or is it satisfactory?

4 DR. HANAUER: Well, my view is that at the top of  
5 the contraindications they mentioned a history of chronic or  
6 severe constipation. The lower part -- maybe it should be  
7 moved up, which is a small point, but it shouldn't be given  
8 in anybody with current constipation.

9 DR. SURAWICZ: And you also have the four days.

10 DR. HANAUER: Which is less defined.

11 DR. SURAWICZ: You also have if it doesn't resolve  
12 within four days, which is another way that people can  
13 measure whether they would fit into the severe constipation  
14 group.

15 DR. HANAUER: I mean, the smart way would be to  
16 move it closer together because we have heard that we want  
17 simplicity for people.

18 DR. LAINE: And, I think that definition is  
19 acceptable that they have.

20 DR. RACZKOWSKI: In our discussions with the  
21 company, I think one of the main points that has come out is  
22 that severe constipation, as intended here and the company  
23 can correct me if I am wrong, but it is intended not to be  
24 assessed by any objective criteria but by the subjective  
25 presentation of the patient saying that he or she -- in this

1 case she has severe constipation, just like if you have a  
2 severe migraine or a mild to moderate migraine.

3 DR. LAINE: But, they now define it here. So, as  
4 Steve says, if you move this up there is a definition of  
5 constipation here.

6 DR. HANAUER: Frankly, we don't know how to define  
7 severe constipation. It is a subjective condition unless it  
8 has a complication.

9 DR. WELTON: I think that is his point. Then it  
10 should be just constipation, not severe constipation.

11 DR. HANAUER: No, we are talking about the  
12 contraindications now, with a history of severe constipation  
13 or current constipation.

14 DR. WELTON: But what I am saying is that he is  
15 suggesting that we should drop the modifier "severe" and  
16 just say with a history of constipation.

17 DR. HANAUER: So, anyone who was constipated 20  
18 years ago shouldn't be contraindicated.

19 DR. WELTON: That is what his question is, his  
20 question is do we know what we are saying, especially in  
21 surgery.

22 DR. HANAUER: The next is sort of no-brainer stuff  
23 to us. Special education programs -- any comments from the  
24 committee? First of all, I will give my personal view that  
25 I thought that what I heard from the sponsor was really an



1 outstanding conglomerate of a risk management program from  
2 your standpoint. I thought it encompassed a lot of things  
3 that we were prompted on coming into the meeting, and  
4 incorporated both education to the patients and to the  
5 physicians. The key, I guess, that we want to know is that  
6 you follow through with that, and that we are being able to  
7 monitor that effect along the way. Any other comments  
8 regarding the education program that we heard about?  
9 Additions?

10 DR. SURAWICZ: Yes, I disagree with you that it is  
11 a no-brainer. I think that maybe this is where we could  
12 focus a few minutes with brain-storming because, while I  
13 like the program that they have, I would like to see them go  
14 a step or two beyond and do something that is really new and  
15 different, that provides the education to patients directly.  
16 They could work with Nancy Norton's foundation. They could  
17 work with specialty societies. There are a lot of ways..

18 I think if it is really going to succeed it has to  
19 be something different than what we already found worked  
20 five percent of the time or didn't work at all. So,  
21 educational materials addressed to patients that would be  
22 written at a grade five level -- really, really simple; lots  
23 of people will understand it; use of visuals, cartoons. Not  
24 just translating into languages but really making it as  
25 simple and consumer oriented as possible. If you look at

1 not drug advertising but the rest of advertising, it is  
2 really, really effective. Maybe building teams with  
3 advertising agencies that know how to get to the entire  
4 population.

5           In one of these books that I read, and I can't  
6 remember which one, there was a list of the specialty  
7 societies that are part of a drug complication reporting  
8 system. What I noticed in that list of all of the specialty  
9 societies was that none of the four GI societies are in that  
10 list at all, and that was a real surprise to me, that all  
11 these other societies have gotten together to do some sort  
12 of reporting of complications. That is not specific to this  
13 drug or this company, but something that we might want to  
14 look at sometime in the future.

15           So, I would like to see really innovative ways of  
16 directing education to physicians, all physicians but  
17 especially GI docs, and your primary care docs. Those are  
18 your two hugest markets. And, then directly to patients.  
19 And, something different. I mean, the examples in the book,  
20 to me, of the patient education material -- I think there  
21 were five or six examples, and there was one that looked to  
22 me, if I were a patient, that I would read. The rest were  
23 tiny little types that looked exactly like what I don't read  
24 as a doctor and would read even less as a patient.

25           DR. HANAUER: I agree. It is a real brainer.

1 That is why she is going to be the next chairman here.

2 DR. LAINE: And to follow up on a point too, since  
3 fortunately or unfortunately a lot of doctors get their  
4 information on drugs from representatives, I mean one of the  
5 things that the companies do extremely well is monitor drug  
6 web visits, to which doctors and what drug they were there  
7 for. Although that doesn't tell you how effective it is,  
8 one of the quantitative things, I guess, the FDA could get  
9 from the company is really having the company commit to X  
10 number of visits per physician or per area to discuss this  
11 particular drug with these particular educational tools, and  
12 just to monitor that and just to make sure that they really  
13 are, indeed, following up with educational programs to  
14 doctors, or educational material.

15 DR. WOLFE: Regarding educational material, also  
16 there are new avenues. You mentioned websites. Websites  
17 can be made to have warnings flashing so people can actually  
18 see them, consumers and physicians. As far as physician  
19 education, I think I can safely assume that all of us here  
20 do give lectures that are occasionally sponsored and we are  
21 given freedom to say what we want to say. On the other  
22 hand, this is something I think should be mandated for  
23 physicians who will be speaking on irritable bowel syndrome.  
24 If they mention drug therapy, they should mention  
25 contraindications during their lectures.

1           The other thing is that there are certain avenues  
2 -- Chris mentioned new ways of doing education. One way,  
3 for example, is computer programs with different case  
4 scenarios for people with certain conditions and how they  
5 should treat them, and the kind of patient who would not get  
6 that kind of drug. So, there are ways to reenforce the idea  
7 of when the drug is appropriately used and when it is not  
8 appropriately used.

9           MR. LEVIN: I just want to reemphasize the  
10 comments about the Internet because that is really where  
11 people are going to get it, and already a tremendous number  
12 of people are getting information from the Internet. I know  
13 a lot of people don't have access to the Internet yet but if  
14 we are looking ten years down the road, that is really where  
15 the information is.

16           Imagine my surprise when I dialed up web MD and on  
17 their home page, in the left-hand banner is an IBS Glaxo  
18 Wellcome connection and you go right to their URL, and it  
19 has information but it is also going to tell you about a new  
20 product that is available for treating IBS. So, I am  
21 concerned that there is a lot of push electronically, and I  
22 am not sure that what people can dial up necessarily  
23 reflects the discussion we are having today about some of  
24 our concerns. For example, if you go on to medscape, which  
25 is another of the major websites, and you go to the drug

1 information patient handout for alosetron, it is a very  
2 mild-manner statement of the risks. So, I think we have to  
3 be aware --

4 DR. HANAUER: Why don't you read it to us, if it  
5 is brief?

6 MR. LEVIN: Sure. First of all, it says,  
7 important note -- this is intended to supplement, not  
8 substitute, for your doctor. It is a one-pager, and under  
9 side effects it is constipation, headache, or stomach upset  
10 may occur. If these effects persist or worsen, notify your  
11 doctor promptly. If constipation occurs, it may only be  
12 temporary. If it occurs, your doctor may recommend ... and  
13 on, and on. I mean, I think it is a very mild-mannered  
14 presentation of the kind of potential severe risks that we  
15 are hearing about today.

16 So, how to deal with the information revolution  
17 and to make sure that the data that many, many millions of  
18 people are dialing up is accurate and presents risk I think  
19 is a critical issue.

20 DR. HANAUER: We understand that.

21 DR. KENT: That is based on the original label.

22 [Laughter]

23 DR. HANAUER: We are not holding you to proactive  
24 standards yet.

25 MR. HAMMES: I want to reemphasize here the role

1 of the pharmacist in all of this, and to include the  
2 pharmacist in this education process. They are the person  
3 that is going to see this patient most frequently. They are  
4 the professional that is likely to be selling them their  
5 laxatives and, if they are any good, they will pick up on a  
6 problem -- if they are selling an OTC that is related to  
7 this, and it is a good way to get the information into the  
8 patient's hands. So, you have to include the education of  
9 the pharmacist first off, and I am really intrigued by this  
10 medication guide thing. I think you need to force the less  
11 than perfect pharmacist to get involved in this. I was very  
12 disillusioned with our young lady who told us she didn't get  
13 any information because she got mail order. I mean, we need  
14 to do something about that.

15 DR. HANAUER: I guess that brings us to medication  
16 guides, and we are not taking a vote but are there opinions  
17 from the committee members?

18 DR. BLUM: I would like to say one thing about the  
19 pharmacists also. The pharmacists are usually in the  
20 community, and if you mention language barriers and being  
21 able to educate, the pharmacist in a foreign-speaking  
22 community usually speaks the language of that community to  
23 communicate with the individual. So, they would be the best  
24 -- better than any type of print media -- to get the  
25 information across. But the pharmacist also has access not

1 only to the OTCs but the herbals that they may be taking,  
2 which could interact with all of this.

3 MR. LEVIN: As a veteran of the med guide wars  
4 over the this last decade, I would like to strongly urge  
5 that the FDA think very seriously about requiring a  
6 medication guide for this product. I think medication  
7 guides, which establish standards for presentation and  
8 content, and format and the graphics are really important,  
9 and I think the most important facet is that it requires  
10 that risk information be up front rather than buried  
11 somewhere down the line. Even though we have this limited  
12 approach to medication guides, I think this is a wonderful  
13 opportunity to use the medication guide regulation as a  
14 public health protection measure.

15 DR. HANAUER: How would you assess that then? How  
16 would you suggest that they assess the benefit if they  
17 imposed a medication guide?

18 MR. LEVIN: I mean, you would have to have some  
19 control to compare it --

20 DR. HANAUER: So, would you suggest a study of a  
21 medication guide in one population versus another to test it  
22 in one managed care group or another?

23 MR. LEVIN: I am not sure that is how the  
24 regulation authorizes medication guides to be used. The  
25 regulation that is currently there, from '98, I think says

1 that you can select up to five to ten drugs and then require  
2 that a medication guide be provided by the manufacturer and  
3 must be dispensed with that drug. So, I don't know if you  
4 can parse that into specific populations. I don't think I  
5 would suggest we need to study medication guides yet again.  
6 We have been there; done that. After all these years of  
7 comments and actions by Congress and the agency, comments by  
8 everybody, the decision was that where drugs present a  
9 certain level of risk it is appropriate to have a medication  
10 guide.

11 DR. HOUN: What would be useful in a medication  
12 guide intervention evaluation would be to do an audit of  
13 pharmacies to see if that is actually happening. Even  
14 though regulation means that there is force of law to  
15 require this, there is force of law to require you to drive  
16 55 miles an hour or less and, you know, whether people do it  
17 or not or whether pharmacists do it or not, that could be  
18 checked on.

19 DR. HANAUER: Do we have data that these guides  
20 make an impact?

21 DR. MORRIS: My name is Louis Morris. I am a  
22 consultant for Glaxo, but I am also one of the veterans of  
23 the medication guide wars. I worked at FDA and was  
24 responsible for heading up that project. Just in terms of  
25 some of these questions, just a couple of comments.



1           The first is, as you might guess, there is no  
2 guarantee that requiring it by FDA regulation actually  
3 results in the distribution of information. As Dr. Ostrove  
4 mentioned, there have been studies done, pharmacy shopping  
5 studies, where people went in, filled prescriptions for the  
6 estrogen patient package insert, which is required by a  
7 specific regulation, and somewhere between 20-40 percent of  
8 people received that document.

9           On the other hand, there is some evidence that  
10 changing the packaging is a more effective solution, and one  
11 of the things that Glaxo did not go into detail over that is  
12 significant to this discussion is that in the proposed new  
13 patient package insert there has been a significant change  
14 in how that would be packaged. The current insert is  
15 attached in a perforated sheet with the physician insert.  
16 The pharmacist has to pull out the physician insert, tear  
17 off the patient package insert and hand it to the patient.  
18 In the current plan, the patient package insert will be a  
19 separate document. It will be attached to the bottle  
20 itself.

21           One of the things that we know from the new work  
22 that is being done on systems and systems approach to  
23 preventing medication errors is that the best solution is  
24 the one that fits most easily into the routine practice of  
25 whoever is distributing it. In this case, what we have is a

1 pharmacist who simply has to pull the bottle down off a  
2 shelf. The bottle for Lotronex, the average size is 60,  
3 which is a month's supply, and the majority of prescriptions  
4 are at that rate. So, all the pharmacist has to do is take  
5 the bottle off and put it in the bag. The pharmacist  
6 doesn't have to do anything special to distribute the  
7 medication guide. It is actually attached to the bottle.  
8 So, I think that packaging solution goes a long way in terms  
9 of concerns about getting it distributed, and I think  
10 historically packaging solutions have been more effective  
11 than regulatory solutions that simply require it.

12           The second point I wanted to make about medication  
13 guides is that one of the downsides of a medication guide is  
14 that there is a standard format, and that if a medication  
15 guide is required, then the company would be required to  
16 follow the standardized format. Currently, the company has  
17 plans to thoroughly test the information to make sure the  
18 message is getting across, and having the flexibility to  
19 actually get the message right is one of the concerns that I  
20 would have where, if it is a medication guide, it has to be  
21 in the standardized format.

22           MR. LEVIN: Lou, I think that is the argument that  
23 is always used with any standard or guideline. When  
24 guidelines are issued, people say, well, medicine is an art;  
25 it is not a science, and you can't stifle innovation. So,

1 there is always a tension between those two sides, and I  
2 think we have to recognize that but one doesn't preclude the  
3 other.

4 I think the standardization is important because  
5 when people go in an survey, even today, the accuracy and  
6 completeness of the voluntary medication guides that are  
7 available in pharmacies there is a lot of important stuff  
8 that is left out. So, at some point in time you have to  
9 develop a standard for what is to be included in a  
10 medication guide and how it is to be evaluated. I think we  
11 have done that ad nauseam since 1995 with medication guides  
12 with all the permutations, with all the parties -- two years  
13 of the Keystone process which I was part of with all the  
14 players at the table, and I don't think we should continue  
15 to debate whether there is a reason to try to have a  
16 standard medication guide. Whether it is appropriate or not  
17 for this particular drug I think is the issue that we are  
18 concerned with today.

19 DR. HANAUER: Go ahead.

20 DR. OSTROVE: Can I just had one additional point  
21 concerning the standardization issue? Dr. Levin is right,  
22 there has been a large history with this. But, I think it  
23 is important to recognize that the regulation permits  
24 exemptions and deferrals and that if, in fact, the  
25 manufacturer has data and is doing research on what best

1 communicates to a particular patient population that shows  
2 that a slightly different format would work better for that  
3 population, that certainly is something that we would take  
4 into account in looking at it. The standardized format is  
5 one that we feel is good because that way people can look in  
6 particular sections to find out where the particular  
7 information is that they are looking for. However, if there  
8 is data, then that is something that we will always take  
9 into account, and we will not be overly restrictive in  
10 determining what is absolutely necessary under those  
11 circumstances.

12 DR. AVORN: There are well established approaches,  
13 very well known to industry when one wants to sell a product  
14 about how do you get information out, how do you make sure  
15 the message got through, is it working and if it isn't  
16 working how do we change it to make sure that it works.  
17 That is fine. I think it is just time to put those well-  
18 established approaches also at the service of getting  
19 information to doctors and patients about problems with the  
20 drug, and that is completely within the purview of what  
21 companies know how to do and I think we should expect that  
22 they will do it. When we have a drug that is on the market  
23 we don't say it makes as a drug, let's just give it to  
24 people and not see if it works. We demand that we know  
25 whether the intervention is working and I think we need to

1 do the same thing with informational interventions.

2 DR. FISHER: Hi. I am Rosemary Fisher. I am  
3 actually here as a consultant for Glaxo. I have a concern,  
4 as Dr. Blum did, about the mail order prescriptions and  
5 things getting across. I actually wonder whether the  
6 attached tear-off on the bottle, 60-pill medication  
7 instruction sheet as opposed to a medication guide would be  
8 a more guaranteed way of known that in the mail order  
9 prescription that would be getting to the patient because it  
10 was attached to the bottle, and not having to have somebody  
11 who is just throwing things in a box, making sure that a  
12 medication guide got in there.

13 DR. WEISS: I am definitely leaning toward the  
14 medication guide, and it is something that the company reps.  
15 had mentioned, that this condition is really something that  
16 the patient goes to the doctor for, and it is the patient  
17 that has to recognize whether or not they have constipation  
18 and seek treatment for it. And, I think that is the kind of  
19 thing that we really need to have in a medication guide,  
20 educating the patients, more than the doctors, to seek  
21 treatment. So, I can see that that is another way to do  
22 that.

23 DR. HOUN: The med. guide could be attached to the  
24 bottle, just as the PPI.

25 MR. HAMMES: And why can't we do both?

1 DR. HANAUER: It sounds like we are doing  
2 everything -- to them.

3 DR. HOUN: So, I guess the consensus is that  
4 people are recommending a medication guide.

5 DR. HANAUER: Not necessarily. I think that we  
6 are hearing a composite effect that Glaxo Wellcome has told  
7 us that they are doing, and I am not certain that adding  
8 everything that you can do up front now is going to be  
9 better, worse or -- my recommendation is to look at a  
10 variety of different means to assess this. You are asking  
11 for risk management which means studying it and imposing all  
12 these things at once, you are not going to know which is the  
13 best way of making an impact right now.

14 I certainly agree also with Dr. Surawicz that the  
15 organization would like to take part -- the American  
16 Gastroenterologic Association, the ACG, and the functional  
17 research group should also get involved with assessments and  
18 education as well.

19 DR. SURAWICZ: I would give the company the  
20 freedom to come up with something better than a med. guide.  
21 If we don't mandate what they do, maybe they will come up  
22 with something really creative and better that will set a  
23 standard for the other companies when this comes up next  
24 time.

25 DR. HANAUER: I would like to see some studies out

1 of it, which is what you are proposing. You can't assess it  
2 unless you are evaluating it in some controlled manner --  
3 different modalities.

4 DR. KRAMER: I do have a little bit of a concern  
5 about a strategy in risk management which would test one by  
6 one by one single interventions, and this where it may come  
7 in handy to talk to a communications researcher or a  
8 psychosocial researcher. My understanding of the field is  
9 that, much like where often one drug at a time isn't the way  
10 to treat the whole disease, you need multiple approaches,  
11 multiple avenues. So, that issue may already have been  
12 sufficiently studied in communications research so that we  
13 know that we should expect poor increments with a single  
14 intervention, one at a time.

15 DR. BLUM: Just one question on the med.  
16 guidelines, does that include the Med Watch number, the  
17 telephone number for patients to report or anyone else to  
18 report in the med. guide, and should that even be considered  
19 as a way of gathering data?

20 DR. OSTROVE: The regulation doesn't include that.  
21 It certainly could be included. That is something that we  
22 are looking at for other regulations having to do with  
23 professional labeling at this point.

24 DR. HANAUER: Besides what we have discussed, does  
25 anyone around the table have ideas or opinions as to how

1 they could improve the benefit side of the drug? We have  
2 talked a lot today about the risk.

3 DR. WOLFE: Just one last idea, there is a  
4 consumer magazine in which patients could actually write  
5 their own stories. I think that is one way of approaching  
6 it. They can actually state what the disease is and what  
7 benefit they have from it, from the different treatments.

8 DR. HANAUER: Anything on the up-side? How can we  
9 improve the efficacy? Any specific opinions? I think you  
10 have heard that the education is to try and limit the use to  
11 the indicated population where we have seen benefit.

12 DR. BLUM: That is the best way because if you  
13 don't give it to the right population you are only going to  
14 get the downside and it is going to give it a bad rep.

15 DR. HANAUER: Any guidance from the committee on  
16 what is the best way to evaluate these interventions? I  
17 think, again, we have heard a number of proposed studies  
18 from the company. There is a whole variety of different  
19 controlled and uncontrolled studies. Anything in addition  
20 or preference from the committee members or our consultants?  
21 Yes, Dr. Welton?

22 DR. WELTON: When you asked me earlier whether I  
23 had any suggestions about what else to look at, it occurs to  
24 me, and I don't know how to do this because I have my own  
25 area of expertise which is very limited, but it occurs to me



1 that although you may not see vasospasm in some of these  
2 studies, you may have a relative ischemia of the mucosa  
3 because the studies that were presented back in November  
4 suggested that increased uptake of water and increased  
5 cellular activity you could have a fixed inflow with a  
6 hypermetabolic state, leading to relative ischemia of the  
7 mucosa. I can't tell you how to study that particularly in  
8 a mouse or a rat model. I have a concern about the PET  
9 scans. As far as I know, that doesn't work because there is  
10 too much background information, but there may be a way to  
11 look at mucosal ischemia and relative hypoperfusion from  
12 metabolic activity.

13 DR. HANAUER: Dr. Houn, any other aspects  
14 regarding evaluation? It is a very open, broad-based  
15 question for us.

16 DR. HOUN: I think one is to reaffirm that  
17 interventions that we do institute, you are looking to have  
18 us and the company evaluate that effect. That is a new step  
19 for FDA because we don't traditionally evaluate a labeling  
20 change or an intervention. So, I think the fact that you  
21 are expecting to happen is something that I want to  
22 reaffirm.

23 DR. HANAUER: Speaking for myself as a member of  
24 the committee, I think that that would be one of the better  
25 ways, and it certainly would be useful to have an

1 independent demonstration of an effect. You are going to  
2 hear about a series of interventions and studies from the  
3 company but I think that as long as you are using this as a  
4 model, and no drug wants to be a model, I am sure, it would  
5 be useful if you developed your own tools to assess and  
6 validate what you are hearing from the other side.

7 DR. HOUN: So, one thing I would like to know is  
8 if we do undertake an independent evaluation of some of the  
9 risk management interventions, I am assuming our labeling  
10 will change to outline some of your recommendations for  
11 contraindications and for indications, and we could  
12 evaluate, either by a chart audit or the automated  
13 databases, in fact, is there, like, ten percent or less of  
14 patients who are receiving Lotronex having  
15 contraindications, conditions, or other medications. We  
16 could do that kind of a study, and is that something you  
17 would be recommending in terms of appropriate and safe use,  
18 that type of an evaluation of practice?

19 DR. HANAUER: Yes, but I would also urge you to do  
20 it by physician specialty because, like in anything else,  
21 the specialists are going to try and push the bubble more,  
22 probably with more experience in doing that than the primary  
23 care physicians. Other comments?

24 DR. WEISS: I would like to see, if you do a  
25 medication guide or package insert, that the patient

1 actually gets it and that they actually understand it. I  
2 think, from what Dr. Rodriguez showed us, that that is  
3 probably an important step to take.

4 DR. AVORN: I think also some survey methodology  
5 of both patients and doctors to understand not just what are  
6 their behaviors but what they know because you want to know  
7 what the doctor is telling the patient in the office about  
8 the side effects. Again, I would just turn to the industry  
9 and ask how they evaluate how well a direct to consumer  
10 advertising campaign is working and use that exact same  
11 methodology.

12 DR. HANAUER: The last point we need to go over is  
13 if you don't do what they say, what next. What do you want  
14 to know, Dr. Houn?

15 DR. HOUN: Let's say we do make contraindications  
16 for people who have had severe constipation or constipation  
17 in the last three weeks -- I mean, those are very defined  
18 terms, and we find that, gee, when we do our evaluation 50  
19 percent of patients in this study who had, in fact,  
20 contraindications were getting the drug, or we look at  
21 adverse event reporting -- right now we have six cases, of  
22 which three had constipation, and if we look at the numbers  
23 of contraindications on adverse events, are they decreasing?  
24 If that doesn't happen and if you could set up some  
25 acceptable levels to achieve, and if those levels are not

1 achieved, what would you recommend? Would you recommend at  
2 that time going back for another year doing education? Do  
3 you recommend -- shall we reconvene the committee next year  
4 to reassess the programs? If we are finding that GI people  
5 have less rates of contraindications, should they be the  
6 ones that prescribe this drug? So, that is what we want --  
7 we want to push you further. You said all these lofty goals  
8 about education, do right, no more, you are going to be  
9 better -- how about if it doesn't happen? What should we do  
10 next?

11 DR. HANAUER: Well, my answer is going to be  
12 simple. It is just what we are asking of the sponsors.  
13 When they come to us with studies and we learn from each  
14 study, and we learn what is good and what is bad and then we  
15 redesign based on that. I think it is going to be difficult  
16 to do that without the specific information that we get out  
17 of these maneuvers. Dr. Ferry?

18 DR. FERRY: Yes, I would like to second that. I  
19 mean, this has been difficult enough today --

20 [Laughter]

21 -- it may not be that clear-cut, you know, a year  
22 down the road either. I think we are going to have to  
23 reassess it at the time. I would have a terrible time  
24 coming up with some pre-plan that if this doesn't work you  
25 have to take some other major step.

1 DR. SIEGEL: One point on that, I am hearing a lot  
2 of tension between, you know, hearing the importance of  
3 really being sure that the drug is prescribed correctly to  
4 the people for whom it is really indicated and, yet, there  
5 may be some groups of physicians who want to push the bubble  
6 a little bit and they really know enough to be prescribing  
7 it in different ways. I think we have to be very clear up  
8 front, if you are looking at that kind of an evaluation down  
9 the line, of whether you really did want to hold the line or  
10 whether it really was okay to push some of this prescribing  
11 a little bit by certain subgroups of physicians or by any  
12 physician. I think that the real issue there comes down to  
13 tying it to the rates of problems that you are seeing at  
14 that point, but it seems to me that if we sit here and say,  
15 well, if we find a problem later on, but we haven't actually  
16 defined up front whether that is a rigid goal that we have,  
17 you are not going to be in a position to say anything  
18 different in a year from now.

19 DR. HANAUER: I don't understand that.

20 DR. SIEGEL: Let me see if I can clarify it. We  
21 have made some points here on how important it is for this  
22 drug to be prescribed precisely for those patients for whom  
23 it is indicated, that is to say, in terms of, you know, not  
24 having a history of constipation and other predisposing risk  
25 factors that would potentially give them problems. Yet, if

1 it is being prescribed -- and the point you made, unless I  
2 misunderstood it was that some specialty practices may have  
3 a patient who does have a history as an alternator, or  
4 something like that, but for whom there is really nothing  
5 else, and they are suffering and they are in terrible shape,  
6 and they really do want to give this patient a trial on the  
7 drug, and then they have a problem. I think that we have a  
8 tension there. I mean, we have said that a critical goal  
9 for this drug is that it be restricted and prescribed  
10 according to --

11 DR. HANAUER: I think you misunderstood what I was  
12 saying, which was that since you are studying it one of the  
13 ways to assess is by physician group and within and without  
14 the indications. So, we are saying very much the same  
15 thing, that we need to evaluate where the complications are  
16 coming and where the benefits are coming.

17 DR. SIEGEL: It may be that we are saying the same  
18 thing --

19 DR. HANAUER: I don't feel tense about it.

20 DR. SIEGEL: That is good. No, my concern is if  
21 you are thinking about what is the next step, it is going to  
22 be confusing data a year from now if we haven't reached some  
23 of the benchmarks that we were aiming towards, but part of  
24 the reason for that is because certain people have really,  
25 with great consideration, decided to use the drug in

1 different ways, and there is no barrier to that happening at  
2 this point.

3 DR. WOLFE: Are you saying that now, for example,  
4 50 percent of the cases were due to people using the drug  
5 incorrectly and next year you want it to be 25 percent only?  
6 So, that shows an improvement and that the program is  
7 working.

8 DR. HOUN: I can't say that I have thought through  
9 exactly what those guidelines will be. I think that we did  
10 talk about having a benchmark and looking towards  
11 improvement toward that benchmark but, at the same time, I  
12 think that there has been no statement here that it should  
13 be in any way restricted so that people won't be using it  
14 for some patients for whom they think it is particularly  
15 indicated, and with an illness like this where people don't  
16 have a lot of choices, I think it is very likely that people  
17 will push those boundaries.

18 DR. HANAUER: How else can we advise you?

19 DR. HOUN: Dr. Wolfe, did you have a question?

20 DR. WOLFE: Are you looking for guidelines from  
21 us?

22 DR. HOUN: That would be great, if people have  
23 some suggestions.

24 DR. WOLFE: The only way to assess this is  
25 looking, I guess, at prescribing practices to see who is

1 getting the drug but also the complications. I think that  
2 is what we are going to be looking at to see if people who  
3 had complications were, indeed, inappropriately prescribed  
4 the drug. Again, the confounding factor, as has been  
5 brought up, is that some people may just want to try  
6 anything they possibly could. Maybe in that case a consent  
7 form would be necessary.

8 DR. BLUM: There is one other thing, trying to get  
9 physicians in the office but most of these complications are  
10 going to occur, especially the constipation -- getting them  
11 to report, say, to Med Watch or someone else because that is  
12 really your population of under-reporting. It will occur in  
13 that population.

14 DR. AVORN: The web MD interface that Mr. Levin  
15 told us about is something which, clearly, the company is  
16 eager to take advantage of, and maybe the agency may want to  
17 talk with the company about other ways in which that  
18 collection of names and addresses, phone numbers and e-mail  
19 address which are being assembled can be used for collecting  
20 data proactively, as well as for marketing, and I think that  
21 could be a very nice tool that could be used for a number of  
22 different purposes.

23 DR. WELTON: Is there a minimum of workup that we  
24 are going to say needs to be done when a diagnosis is made -  
25 - again, ischemic colitis?



1 DR. HANAUER: By the physician?

2 DR. WELTON: If a patient calls in and says they  
3 are having some bleeding, does the prescribing physician  
4 have to work that up?

5 DR. HANAUER: That can't be regulated. Do you  
6 have a comment?

7 DR. GURWITZ: Yes, the only thing I just want to  
8 reiterate as far as next steps is how important it will be  
9 to find out what the patients and providers understand about  
10 the educational program. If you see a reduction in  
11 complications, then you can say the program is working and  
12 that would be okay, without understanding potentially what  
13 it was about it that worked but just know that is worked.  
14 So, it would be particularly important if you get back here  
15 in a year and you find out things aren't better, and if you  
16 don't know what the providers and patients understand  
17 despite all your databases and stuff you are going to have a  
18 hard time deciding what your next steps are going to be  
19 because you are not going to know what part of the message  
20 they did or did not get.

21 DR. HANAUER: Okay. I want to thank again the  
22 company, Glaxo Wellcome, for their presentations and their  
23 willingness to work with us and the committee to try and  
24 compact the discussions. I hope we have not influenced in a  
25 negative way. I think we squeezed this lemon as much as you

1 can get out of it today.

2 I want to thank personally Dr. Talarico for  
3 supporting me during my chairmanship here, and Dr. Gallo-  
4 Torres, and we look forward to the reign of Dr. Surawicz for  
5 the next meetings. Thank you, all. Have a good night.

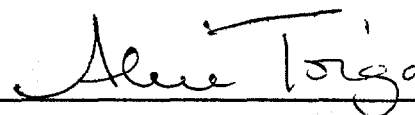
6 DR. HOUN: Thank you so much.

7 [Whereupon, at 3:30 p.m., the proceedings were  
8 adjourned.]

9

**C E R T I F I C A T E**

I, **ALICE TOIGO**, the Official Court Reporter for Miller Reporting Company, Inc., hereby certify that I recorded the foregoing proceedings; that the proceedings have been reduced to typewriting by me, or under my direction and that the foregoing transcript is a correct and accurate record of the proceedings to the best of my knowledge, ability and belief.

A handwritten signature in cursive script that reads "Alice Toigo". The signature is written in black ink and is positioned above a horizontal line.

ALICE TOIGO

**0**

0-100 23:9  
0-3 195:8  
0.3 147:25; 151:16  
0.4 44:10, 15  
0.5 44:12; 151:21  
0.8 151:16  
0.9 44:13

**1**

1 29:6; 34:6, 10, 11, 23;  
35:4; 36:2; 40:7, 8, 16;  
43:1; 112:15, 20; 113:24;  
116:16; 117:4, 7, 13, 17;  
118:2, 15, 22; 119:16;  
121:10; 122:10; 129:21;  
150:24; 151:9, 13, 15, 15,  
18; 173:17  
1.4 55:19  
1.5 42:10  
1/10,000 145:5  
1/1000 145:5; 194:21;  
195:2, 15, 16, 23; 196:14,  
24; 197:12; 203:11  
1/1500 195:23  
1/4 161:4, 8; 162:5  
1/450 195:9  
1/750 194:25; 195:10  
1/900 195:1; 196:14, 19  
1/980 40:11  
10 35:7, 11; 41:24; 42:15;  
43:23; 45:25; 70:21;  
113:12; 114:3; 129:7;  
164:19  
10,000 52:6; 54:21;  
56:12; 73:14; 87:11; 99:15  
10-20 111:15  
100 158:3; 164:23; 203:4  
11 45:21; 112:22  
110,000 42:24  
115,027 77:3, 5  
11:10 106:11  
12 20:17; 22:5, 8; 29:5;  
32:7; 79:18; 113:24;  
116:22, 25; 117:1; 118:20,  
22; 129:22; 159:11, 24;  
176:4; 212:25  
12-A30 4:21  
12-month 205:6  
12-week 70:17; 82:21  
120,000 187:15  
121,000 187:9  
123 164:21  
12:45 163:10  
13 79:18  
13.5 22:8  
130 43:5  
130,000 34:12; 40:17;  
45:6; 76:24; 77:2, 4  
14 173:18

14,478 43:4  
1400 151:5  
15 70:20; 112:25; 166:25;  
167:4  
15,000 77:4, 5  
15-minute 106:11  
16 13:10; 41:3; 113:24;  
117:4  
16th 15:22; 33:21  
17 39:7; 121:14, 15;  
160:25  
17,000 153:19  
18 4:17; 21:15; 38:21;  
173:19; 194:7  
180 111:18  
181 111:18  
188 42:25  
19 113:2, 23; 116:22  
1977 128:24  
1989 55:9  
1990 53:4  
1991 172:20  
1993 152:10  
1994 152:14  
1995 227:11  
1998 152:22, 25; 153:8,  
18; 154:8  
1999 13:10; 33:21;  
142:23  
1:30 163:8, 11

**2**

2 36:2; 38:9, 20; 44:25;  
45:24; 112:23; 113:15, 24;  
114:2; 116:20; 117:3, 13,  
14, 17; 118:2, 17; 119:17;  
120:12; 121:10, 25; 122:6;  
151:1, 14, 16  
2-3 119:17  
2-day 38:21  
2-fold 44:21  
2-week 29:5  
2.6 151:15, 18  
20 77:24; 79:18; 216:17  
20,000 58:10; 73:14;  
99:15  
20-40 225:7  
20-year 206:15  
200 70:18  
2000 13:9; 34:6; 40:16;  
42:24; 129:21; 160:18  
201 45:21  
208(b) 4:17  
21 38:3  
22 41:5; 83:17; 117:20  
23 38:7; 164:19  
2307 150:25  
24 151:8  
25 128:18; 239:5  
25,000 58:10  
25-30 129:6

250,000 145:14  
259 111:21  
26 154:2  
27 34:23; 36:24; 41:14;  
87:1, 9; 121:12; 154:4;  
161:3  
2823 151:3  
29 153:25; 154:4  
2C19 90:24; 91:12  
2C9 91:13

**3**

3 17:25; 32:13; 40:9;  
41:16; 44:11, 15; 45:9;  
74:3; 113:1, 6, 15, 25;  
114:2; 116:23, 25; 117:3,  
6, 12, 18, 18; 118:2, 7, 11,  
15; 121:6, 9, 10, 11;  
122:14; 129:14; 130:11;  
148:2; 151:14, 16, 19, 20  
3-fold 44:9, 17, 25  
3-month 112:13  
3/6 39:20  
30 128:18  
30-35 32:24  
3000 34:8; 40:6  
3001 29:20, 25; 161:11,  
14  
3002 29:21; 30:6; 113:20;  
161:14  
33 117:18  
35 71:3; 117:22  
3500 195:7  
39 112:20; 113:7  
3:30 12:13; 242:7  
3A4 90:24; 91:1, 8; 153:1

**4**

4 32:14; 35:15, 19; 36:3;  
37:20; 38:4; 40:4; 41:25;  
45:23; 56:13; 116:16;  
118:21; 129:19; 151:20  
4-20 20:1  
4-day 35:20  
4-week 29:8  
40 36:21; 90:17; 111:12;  
112:17; 113:22  
41 90:15; 113:1; 173:20  
42 87:1  
43 112:24  
44 24:8  
45 151:10; 152:3  
47 113:22  
48 161:2  
48-year 37:21  
4800 153:19

**5**

5 22:8; 34:24; 40:18;  
45:23; 116:17; 164:20  
5-day 41:25; 43:24  
50 90:17; 111:12; 112:21;  
113:7; 235:18; 239:4  
50-year 38:2  
500 70:20  
51 160:24  
53-year 119:5  
54 120:13  
54-year 36:11  
55 181:18, 18; 224:16  
56-year 36:19  
57 154:4  
58 112:23  
5HT3 28:17, 18; 95:15, 16

**6**

6 35:6; 111:22; 117:1, 5;  
121:5; 129:13; 130:10;  
160:2, 3; 164:23  
6/8 24:14  
60 87:8; 113:1; 154:3;  
226:2  
60-pill 229:6  
600 28:24; 31:17  
61 161:6  
65 35:1; 180:17  
68 113:8; 114:7; 160:25  
68-year 38:8  
6852 34:10; 40:10  
69-year 41:3

**7**

7 36:12; 37:22; 40:10;  
113:13; 116:19, 21, 25;  
117:1; 121:4, 5, 15;  
129:12; 130:10  
7.3 151:18  
70-year 97:11  
70s 200:20  
72-year 39:4; 97:25  
74 21:11  
75 35:3; 117:19; 161:3  
75-year 206:18  
750 40:8  
78 113:8  
78-year 185:4  
783 32:6

**8**

8 23:10; 39:2; 83:18;  
84:17; 113:13; 116:20;  
117:2; 118:21, 21; 129:22  
8-13 148:4

**9**

80 114:7; 117:19  
80-year 185:23  
8000 153:20  
85 161:7  
88 35:20  
9 13:9; 35:18  
9.3 151:19  
900 25:7  
93 43:3  
95 42:23  
97 150:1; 151:1  
98 151:4; 153:17; 223:25  
99 43:3

**A**

A44 93:6  
abd 88:8  
abdomen 41:19  
abdominal 19:16, 21;  
37:5, 6; 38:11; 41:5; 46:1;  
87:24; 112:6; 115:7, 10,  
14, 16; 120:11, 13; 121:17,  
18, 19; 122:12, 16, 17, 18;  
137:22; 186:9; 212:14  
ability 103:22; 210:13  
able 67:19; 68:6; 69:10;  
103:16; 127:9; 145:4;  
161:9; 166:1, 2; 167:14;  
168:6; 170:11, 15; 171:3;  
178:12; 181:5; 183:23;  
217:6; 222:21  
abnormal 118:8; 212:18,  
20, 20  
abnormalities 15:25;  
19:23; 173:15  
abnormality 180:18, 19  
abscess 39:10; 97:16;  
121:23; 206:19  
absence 204:11  
absenteeism 22:4, 7;  
27:21; 28:6; 175:2  
absolutely 103:1, 16;  
141:5; 160:7, 13, 20;  
166:7; 196:3; 213:1;  
228:10  
abstract 103:22  
abstraction 51:13; 149:8  
abut 11:14  
academic 19:11  
accept 190:5; 195:11;  
196:17; 198:15  
acceptable 10:23;  
195:17, 23; 198:23;  
203:12; 215:19; 235:25  
acceptance 64:20  
accepted 70:23  
access 187:18; 193:1;  
220:13; 222:25  
accommodate 175:9

accomplish 69:9; 154:18  
accomplished 14:1  
accomplishing 60:22  
dance 4:17  
ording 24:16;  
128:19; 135:11; 177:23;  
238:10  
Accordingly 16:3  
account 228:4, 9  
accrue 54:23  
accuracy 227:5  
accurate 75:21; 131:18;  
139:5; 204:5; 221:18  
accurately 14:12  
ACG 230:16  
achieve 207:14; 235:25  
achieved 70:19, 20,  
107:23; 136:2; 161:15;  
236:1  
achieving 149:18; 197:8  
acid 161:2  
across 23:17; 24:14;  
48:25; 100:13; 151:18;  
222:25; 226:18; 229:5  
ACs 91:2  
action 14:18; 18:6; 50:2;  
61:15  
actions 59:22; 63:8;  
66:18; 224:7  
ive 93:5; 121:24;  
ely 14:6  
activities 11:2; 17:1, 11;  
49:19; 140:24  
activity 30:7; 74:25; 96:6;  
233:5, 12  
actual 10:7; 48:16; 50:22;  
52:1; 91:13; 99:11; 105:6;  
172:7  
actually 10:3; 21:23;  
26:10; 41:12; 78:11;  
82:21; 84:11; 85:6; 87:7;  
89:3, 13; 90:12, 25; 93:12,  
14; 94:4; 100:7; 136:6, 21;  
142:21; 146:16; 148:19;  
158:19; 159:22; 160:17;  
162:23; 163:2; 165:21;  
169:23; 170:11, 15; 177:5;  
182:16, 25; 189:2; 194:10;  
198:20; 203:1, 4; 208:17;  
210:4; 219:17; 224:13;  
225:2; 226:7, 19; 229:3, 5;  
232:4, 6; 235:1, 1; 237:15  
acute 40:12, 19; 43:17;  
51:19; 71:15, 18; 103:14;  
150:3, 4  
ad 227:11  
165:14; 198:1; 208:7  
g 79:20; 179:14;  
addition 22:20; 23:2;  
58:1; 60:2; 72:2; 74:17;  
75:18; 76:12; 78:10; 88:4,  
7; 90:4; 131:11; 145:1;  
173:5; 179:1; 213:15;  
232:19

additional 5:14, 20; 16:7;  
45:5, 25; 56:13, 20; 57:6;  
63:9; 65:10, 18; 77:9;  
107:1; 116:20; 124:6, 8;  
127:12; 129:22; 130:14;  
143:6; 227:20  
additionally 60:15  
Additions 217:9  
address 5:11; 14:14;  
15:7; 49:20; 50:20; 58:6;  
64:19; 65:18; 80:22;  
88:21; 100:15; 133:25, 25;  
180:10; 201:25; 240:19  
addressed 51:23;  
144:24; 183:17, 22;  
217:21  
addresses 72:8; 240:18  
addressing 13:21; 20:11  
adds 131:20  
adequate 9:8; 29:12, 13,  
15, 22; 31:24, 24; 32:1;  
93:14, 17; 112:5; 161:11;  
162:12  
adequately 72:8; 176:4;  
210:17  
adherence 49:13; 138:10  
adhesed 37:7  
adhesions 37:5; 201:2;  
213:14  
adjourned 242:8  
adjusted 21:13; 25:16,  
16  
adjustments 175:9  
administered 110:13  
Administration 8:14;  
47:15; 52:8; 57:2, 19; 58:2,  
23; 108:24, 25; 109:11;  
111:5; 115:19, 21; 138:14;  
170:23  
administrative 166:23  
administrator 169:8  
admission 38:22  
admitted 37:1; 38:5;  
41:7; 186:9  
ads 127:8, 9, 10  
adult 25:7  
advance 47:20; 58:13  
advantage 162:10;  
210:14; 240:16  
advantages 209:21  
adverse 9:9, 12; 10:23;  
11:12; 17:12, 17; 18:7;  
34:23; 36:1; 39:18; 48:1;  
49:25; 57:8; 74:4; 76:3;  
108:4; 116:1, 3, 7; 117:13,  
20; 118:21; 121:12; 124:9;  
126:6, 9, 11, 12; 127:5, 17,  
25; 128:20; 129:5, 12, 24;  
130:12; 131:18; 137:19;  
144:23; 145:9, 13, 19;  
146:7, 10, 12, 14; 147:9,  
10, 16; 148:3, 5; 150:4;  
194:17, 20; 197:12;  
235:21, 23  
advertising 9:22;  
107:13; 124:5; 127:8;

131:11, 12, 17, 17; 193:18,  
21; 218:1, 1, 3; 235:10  
advice 10:15; 11:4  
advise 177:8; 239:18  
advising 60:25; 75:6  
advisories 130:20  
advisory 15:22; 28:12;  
33:21; 43:11; 45:12;  
58:21; 106:18, 20; 110:10,  
19; 112:10; 114:17;  
115:23; 116:6; 118:12;  
124:17; 129:3; 133:4;  
143:24; 150:21; 154:15  
advocacy 11:25; 131:7  
advocate 160:3; 164:18  
advocates 10:17  
advocating 208:9  
AERS 146:19, 23  
affect 138:2, 7, 12  
affected 25:25; 27:19;  
88:16; 115:16  
affects 20:2; 196:4  
affiliated 135:2  
affirmative 173:25; 174:5  
afflict 70:10  
afflicted 76:2  
afford 51:8  
afraid 163:1; 199:2  
Africa 98:14  
afternoon 133:22; 134:4;  
164:1  
afterwards 28:10;  
153:21; 158:20  
again 25:5, 14, 20; 26:6;  
27:2; 31:8, 25; 33:7, 23;  
38:17; 39:24; 40:14, 20;  
41:18; 42:15; 43:24;  
83:12; 84:19; 87:8; 89:14;  
90:13; 96:10, 13; 99:4, 12;  
103:21; 106:3, 7; 110:15;  
112:15; 113:20, 25;  
115:13; 116:25; 117:12;  
118:2, 20; 119:22; 128:24;  
129:17; 130:8; 135:1;  
136:14, 24; 138:3; 141:18;  
146:12; 150:12; 158:6;  
159:4, 25; 161:4; 170:17;  
172:2, 5; 175:4; 179:6, 14,  
17; 183:9, 13; 184:2;  
187:17; 189:11; 194:15;  
197:19; 208:8, 15; 214:8;  
224:5; 232:17; 235:8;  
240:4, 25; 241:21  
against 70:10; 72:24;  
75:6, 7; 87:1  
age 21:13; 25:16; 53:19;  
144:19; 181:18; 188:7, 9;  
194:7  
aged 144:8  
agencies 155:2; 218:3  
agency 4:13; 13:8; 14:19;  
16:5; 17:18; 106:10;  
136:21; 157:11; 189:12;  
196:12; 202:15; 205:16;  
207:4, 21; 224:7; 240:16  
agenda 4:12, 23

agent 160:1, 22; 161:2, 5  
agents 20:10; 31:21;  
32:3; 73:18; 74:3; 128:15;  
157:17; 160:6, 7  
aggregate 44:16; 184:7  
aggressive 79:6  
Aging 7:15  
ago 21:7; 23:7; 86:1;  
136:3; 167:4; 213:4, 22;  
214:5, 6, 7; 216:18  
agree 17:19, 20; 33:16;  
72:18; 85:17; 90:12; 99:1;  
102:6; 192:23; 196:9, 21;  
198:4; 200:23; 211:12;  
218:25; 230:14  
agreed 34:1, 5; 64:14  
agreeing 61:3  
agreement 52:8; 72:15;  
136:20; 161:22  
agrees 178:3; 189:6  
ahead 165:15, 19; 166:9;  
184:11; 196:6; 198:6;  
227:19  
aid 62:4  
aim 25:3  
aimed 47:12  
aiming 100:9; 238:23  
Alabama 166:22  
alarm 199:24  
algorithms 53:8; 149:5, 6  
alkaline 44:20; 118:10  
Allan 57:21  
alleged 146:14  
Allen 18:14; 28:3, 4  
allergies 45:10  
allow 5:5; 51:9; 68:25;  
69:3  
allowed 191:9  
allows 173:8  
alluded 124:7; 148:14;  
149:4, 17; 193:23; 211:17  
almost 25:7, 25; 154:3;  
165:10; 170:1; 186:20  
alone 10:9  
along 10:16; 37:7; 62:10;  
64:9; 69:7; 162:25;  
173:11; 205:2; 208:18;  
213:22; 217:7  
alosetron 28:14, 17, 21;  
29:6; 30:1, 5, 17, 19, 25;  
31:2, 6, 14, 20; 32:2, 8, 21;  
33:3, 18; 34:5, 7, 8, 11, 12,  
21, 24; 35:17; 36:5, 12, 17,  
25; 37:22; 38:3, 10, 10, 20;  
39:7, 14, 18, 20, 24; 40:5,  
7; 41:4, 7, 25; 42:14, 16;  
43:21, 23, 24; 44:2, 15, 23;  
45:3, 6, 9, 17, 17; 46:3, 8,  
16; 91:12; 96:13; 118:13;  
119:16; 159:14; 160:12,  
14; 221:1  
alosetron-treated  
44:12, 18  
ALT 44:9, 11, 14, 17, 24;  
118:10

altered 19:16, 17, 19;  
133:10, 10  
alternate 84:12  
alternating 29:4; 39:6;  
109:21; 121:11; 213:25;  
214:2, 15  
alternative 33:22; 127:21  
alternator 84:8, 21, 23;  
85:18; 88:14, 22; 238:3  
alternators 80:18; 81:6;  
83:4, 5, 5, 24; 84:17, 20,  
25; 85:3, 10, 11; 88:15, 15,  
17; 183:12; 188:5; 189:5;  
213:24  
Although 35:11; 37:9;  
93:2; 136:9; 144:21;  
147:12; 180:13, 24;  
181:5; 187:9; 192:4;  
209:9; 219:7; 233:1  
ALTs 45:17  
always 22:21; 181:9;  
205:22; 226:23; 227:1;  
228:8  
American 173:15;  
230:15  
Americans 172:15  
amino 185:9; 186:1, 3,  
10, 17, 19, 24; 187:11, 15  
among 53:11; 145:24;  
151:14; 175:18; 203:12  
amount 102:15; 162:3;  
204:24  
amplitude 96:8  
analyses 55:2; 109:18;  
112:7; 153:22  
analysis 57:8; 93:14, 18;  
112:9  
analytic 183:2  
analyze 34:4  
anaphylaxis 185:22  
anasarca 185:7  
anatomic 180:17, 18, 22  
and/or 33:16; 43:16;  
46:12; 80:17; 108:24;  
123:24; 130:16; 212:15;  
213:13, 17, 18  
Andrews 18:17, 17;  
46:19, 22, 25; 59:5; 60:13;  
69:8; 78:6; 91:7; 101:21;  
102:24; 103:1; 104:4  
anecdotal 136:22  
Angeles 6:11  
animal 95:23; 127:3;  
197:17  
animals 95:24  
announcement 4:9  
announcing 62:1  
annual 175:3  
annually 137:12  
answered 62:14  
antagonist 28:18  
antibiotic 119:9  
antibiotics 39:11  
anticipate 12:13; 61:2  
anticipation 33:12; 143:7

94:5; 134:8; 135:22;  
155:6; 157:24; 167:3;  
170:9, 14; 174:3; 176:6;  
181:1; 182:24; 195:14;  
203:3; 225:23; 227:25;  
230:13; 232:12, 16  
**bet** 134:11  
**better** 23:9; 24:15, 23;  
26:21; 27:8, 13; 54:24;  
56:5, 20; 79:25; 80:3, 7;  
82:25; 98:24; 152:1;  
157:16; 161:8; 170:12;  
213:8; 222:24; 228:2;  
230:9, 20, 22; 233:24;  
236:9; 241:15  
**beyond** 178:20; 190:9;  
217:14  
**big** 135:12  
**bile** 186:2  
**bilirubin** 44:21, 25;  
118:11  
**bills** 175:3  
**biochemical** 19:23  
**biological** 145:20  
**biopsy** 41:11; 77:13  
**birth** 90:1; 179:5, 11, 19;  
180:1  
**Bismal** 128:17, 17; 160:5  
**bit** 5:25; 100:8; 127:9;  
148:2; 181:17; 201:10;  
202:22; 208:22; 231:4;  
236:11  
**black** 17:18, 19; 72:12,  
16, 20, 21, 25; 74:7; 75:1,  
5, 9; 20, 22; 92:3, 5, 8, 10,  
13, 23; 129:2, 3; 152:19;  
157:8; 197:20; 198:1;  
211:5, 7  
**bleeding** 119:18, 20;  
120:10; 241:3  
**bloating** 19:21; 174:12  
**blood** 57:18; 94:20, 25;  
95:13; 96:1, 2, 12; 158:10,  
13; 187:16  
**bloody** 77:7, 11; 120:11;  
137:22  
**blue** 5:21, 22  
**BLUM** 6:18, 18; 76:23,  
24; 100:17, 18; 103:24;  
158:1, 2; 166:13, 16;  
183:17; 184:1; 187:14;  
192:23; 206:5; 222:18;  
229:4; 231:15; 232:12;  
240:8  
**Board** 6:23  
**boards** 102:12  
**bodily** 23:12; 26:8, 15, 20  
**body** 168:3  
**boiling** 5:9  
**boiling** 26:25  
**bold** 210:7  
**bolded** 74:7; 75:18  
**bolding** 139:24  
**bombarded** 210:18  
**book** 218:19

**books** 218:5  
**boss** 167:8  
**Boston** 7:8, 18; 55:6  
**both** 16:11; 20:6; 28:14,  
19; 29:3; 32:20; 44:18;  
47:19; 53:5; 54:11; 55:3,  
25; 78:19; 90:24; 112:13;  
123:23; 124:12, 21;  
194:22; 209:3; 217:4;  
229:25; 235:5  
**bottle** 225:19; 226:1, 2, 5,  
7; 229:6, 10, 24  
**bottles** 63:12  
**bottom** 100:25; 214:19  
**boundaries** 239:17  
**bowel** 8:19; 13:4; 15:12;  
19:16; 28:1; 29:4, 15;  
31:22; 35:8, 9, 16, 19, 21;  
37:2, 10; 38:4; 41:21; 42:2;  
51:18; 59:14; 63:5; 64:22;  
65:19; 69:24; 81:4, 5;  
82:21; 89:15; 96:23;  
97:25; 106:24, 25; 108:16,  
17; 110:4, 6, 15; 120:15;  
121:24; 122:17, 18, 23;  
123:13; 128:16; 132:14;  
144:13; 149:10; 156:19;  
157:23; 164:5, 7; 165:14;  
166:25; 167:17; 168:21,  
24; 169:18; 180:15, 16;  
199:1; 206:5, 16; 211:13;  
212:12, 18, 19; 213:17, 18;  
219:23  
**box** 17:18, 20; 72:12, 16,  
20, 21, 25; 74:7; 75:1, 5;  
91:20, 22; 92:3, 8, 11, 13,  
23; 129:2; 152:19; 157:8;  
197:20; 198:1; 208:7;  
210:5; 211:1, 5, 7; 229:11  
**boxed** 74:13; 126:20, 22;  
127:6, 7, 14, 16; 128:3;  
129:16; 131:21; 207:17;  
208:1, 4, 22; 209:5, 9, 13,  
21  
**boxes** 92:5; 129:3  
**brain** 173:8  
**brain-gut** 173:4  
**brain-storming** 217:12  
**brainer** 218:25  
**brainstorming** 209:19  
**branches** 96:5  
**Brandt** 43:9; 76:16;  
180:5, 5; 181:7; 182:7;  
195:2, 4, 13  
**breadth** 50:18; 98:10  
**break** 105:23; 106:11;  
163:6  
**breakdown** 85:8  
**brief** 19:4, 6, 13, 14;  
35:16; 69:20; 87:22;  
106:12; 123:6; 131:17;  
144:15; 202:22; 221:5  
**briefing** 5:16, 21; 14:19;  
15:21; 17:25; 18:2; 36:9;  
40:24; 45:5, 22; 75:15;  
95:22; 101:23; 111:18, 19,  
21; 124:2

**briefly** 12:12; 36:7; 44:4;  
116:7; 117:15; 118:3;  
121:9; 122:10; 124:11;  
125:1; 134:7, 18; 156:10;  
210:23  
**Brigham** 7:18  
**bring** 5:15; 69:17; 99:20;  
159:3; 209:13, 22  
**brings** 137:2; 222:15  
**British** 175:25  
**broad** 16:24; 103:13;  
143:24; 214:5  
**broad-based** 233:14  
**broader** 85:14; 183:10,  
13; 193:25  
**brochure** 62:7; 63:4, 17;  
64:9  
**brochures** 63:2  
**brought** 5:20; 240:5  
**bubble** 234:21; 237:5  
**Building** 4:21; 218:2  
**builds** 47:17  
**bullet** 139:7  
**burden** 15:3, 10; 18:13,  
25; 19:2, 5; 20:24, 25;  
21:4; 22:3, 11, 19; 27:17;  
46:7; 69:24; 174:20; 182:5  
**bureau** 66:12  
**buried** 223:10  
**business** 10:23; 65:14;  
198:19, 20

**C**

**C** 153:6, 20; 154:4  
**calculated** 21:4  
**California** 7:24  
**Call** 4:2, 3; 9:3; 64:19;  
66:4, 6; 82:20; 131:20;  
137:3; 166:3  
**called** 111:14; 135:15;  
145:9; 167:17; 191:13;  
193:23  
**calling** 77:13  
**calls** 66:5; 241:2  
**came** 22:7; 23:23; 40:22;  
54:6; 77:13; 109:17;  
135:8; 149:11, 12; 168:14;  
185:2, 4, 24  
**campaign** 235:10  
**can** 20:3, 5, 25; 21:2, 4;  
22:12, 19; 27:17, 19, 20;  
29:25; 32:1; 44:22; 50:2, 8,  
11, 14; 51:10, 13; 64:19;  
65:18; 73:17; 74:4; 80:21;  
81:11; 82:23; 85:5; 86:14;  
87:10; 88:11, 25; 89:21;  
91:4; 99:9; 102:15; 103:3,  
10; 104:2; 110:11, 12;  
111:20; 113:7; 114:19, 23;  
116:11; 124:19; 125:5, 11,  
18; 126:21, 24; 130:14, 16,  
25; 131:11, 12, 16, 24;  
132:3, 6, 7, 7; 134:11;  
135:15; 136:6, 7; 141:12,

17, 21; 142:1, 4, 7; 145:21;  
146:16, 16; 147:25;  
155:20; 158:20; 159:18;  
167:1, 20; 170:23; 172:8;  
19; 173:10; 174:2; 175:12;  
177:1; 180:18; 184:9, 15;  
187:9; 189:19; 195:6, 14,  
22; 200:11, 17; 201:12, 14;  
207:10; 209:22; 215:12,  
23; 219:17, 17, 19; 220:22;  
224:1, 4; 227:20; 228:5;  
229:21; 230:8; 232:6, 8;  
237:20; 239:18; 240:19;  
241:11; 242:1  
**cancer** 174:20  
**candidates** 59:13, 16;  
62:6; 69:14  
**captures** 23:10  
**car** 168:2  
**card** 62:9; 64:5, 13; 65:14  
**cardiovascular** 152:20  
**cards** 62:3, 4  
**Care** 8:7, 21; 12:1; 15:9;  
20:17, 18; 21:18; 23:25;  
38:6; 52:25; 53:1, 16; 98:2;  
150:11; 153:13; 172:14;  
173:17; 176:6; 192:3, 8, 8;  
193:11; 218:17; 223:22;  
234:23  
**cared** 192:3  
**careful** 102:19; 103:5;  
128:3; 145:24; 147:2;  
162:2  
**carefully** 16:9; 58:11;  
89:9; 90:11; 146:8; 197:16  
**caring** 37:13  
**Carolina** 66:7  
**carried** 93:20; 112:8;  
168:2, 2; 176:8  
**cartoons** 217:23  
**case** 36:18, 18; 38:2, 8;  
39:4; 40:8, 22, 25; 41:2;  
43:1, 19; 45:7, 8, 12; 51:7,  
8; 55:4; 56:2; 77:8; 88:19;  
97:13; 99:23; 103:12;  
108:11; 117:7, 8, 9;  
118:23; 119:1, 12, 23;  
120:3, 17, 23; 121:1, 5;  
122:10; 123:1; 135:16;  
136:14; 137:18; 138:4;  
144:20; 146:20, 22;  
149:22, 25; 155:20;  
186:14; 187:4; 188:24;  
198:1; 199:20; 216:1;  
220:3; 225:25; 240:6  
**case-controlled** 183:1  
**cases** 16:17; 33:19, 19,  
23; 36:8, 9; 37:16, 20;  
40:11; 42:21, 25; 43:5, 17;  
45:23, 23, 24; 51:20, 25;  
56:4; 71:13, 15; 77:7, 25;  
78:12, 13; 80:23; 86:23;  
90:17; 99:2; 103:14, 15,  
17, 18, 18; 116:15, 16, 19,  
20, 23; 117:2, 4, 6, 15;  
118:11; 119:2, 4, 10;  
122:14, 22; 129:19; 130:4;  
134:12; 135:4; 139:9;

146:19, 24; 147:1, 2;  
148:9, 11, 21; 179:10;  
180:17, 22; 181:12, 13;  
184:24; 195:5, 8; 200:12;  
201:1; 203:5; 235:21;  
239:4  
**cast** 148:23  
**casting** 51:24  
**casual** 110:7, 16  
**categories** 116:14  
**categorize** 81:9  
**categorized** 116:11  
**category** 13:6; 106:8;  
207:9  
**caught** 188:21; 210:14  
**causal** 126:17; 129:4, 18,  
25; 130:8; 199:23; 201:9  
**causality** 145:18; 147:2,  
12  
**cause** 20:4; 74:1, 4; 98:4,  
5, 5; 99:9; 145:21; 147:7;  
186:24; 187:1, 7  
**caused** 76:2; 95:20  
**causes** 76:1; 162:4  
**causing** 196:14; 203:4  
**CDC** 99:16  
**celecoxib** 70:19  
**cell** 57:16; 95:9  
**cells** 94:21; 95:3  
**cellular** 233:5  
**Center** 4:14; 7:20; 15:8;  
66:4, 4, 6; 77:24; 192:25  
**Centers** 49:14  
**central** 173:2  
**Cerebral** 6:19  
**certain** 81:16; 82:4, 6;  
102:15; 128:6; 136:10;  
138:22; 158:23; 182:18;  
191:7; 194:21; 207:21;  
220:1, 4; 224:9; 230:7;  
237:11; 238:24  
**certainly** 18:24; 85:17;  
97:24; 98:4; 102:16;  
104:6; 123:16, 17; 134:2;  
144:16, 16; 174:22;  
189:17; 190:6; 191:3;  
208:3; 210:9; 228:3;  
230:14; 231:21; 233:25  
**CERTS** 49:14  
**cessation** 132:19;  
159:14; 186:21; 204:16  
**chains** 63:16  
**Chairman** 6:20, 22; 76:9;  
123:19; 219:1  
**chairmanship** 242:3  
**challenge** 51:22; 118:17  
**challenges** 51:17, 17, 23  
**challenging** 155:23;  
203:9  
**chance** 98:19  
**change** 14:17, 18; 33:16;  
40:13; 43:15; 46:12; 54:8;  
83:6, 10; 96:12; 133:13;  
150:17, 18; 152:3; 154:5;  
187:6; 193:14; 201:15;

225:13; 228:16; 233:20;  
234:10  
**changed** 14:16; 79:19;  
167:15  
**changes** 16:3, 4; 18:4;  
60:25; 67:20; 68:7; 69:4;  
79:24; 107:12; 149:16;  
150:10; 152:25; 154:8;  
186:18, 19, 25; 187:11;  
207:16  
**changing** 91:16; 225:10  
**channels** 104:22  
**characteristics** 47:16;  
120:6  
**characterize** 53:19, 21;  
56:4  
**characterized** 87:23;  
174:10; 212:13  
**charge** 12:7, 15; 177:3;  
212:6  
**charged** 177:13; 209:18  
**charges** 177:5  
**chart** 234:12  
**Chattanooga** 164:17  
**check** 62:4; 168:5  
**checked** 90:6; 224:18  
**checks** 102:13  
**Chey** 76:16  
**Chicago** 7:5  
**Chief** 7:16; 12:24  
**children** 141:1  
**choice** 168:11  
**choices** 239:16  
**choose** 127:21  
**chose** 119:4  
**Chris** 220:2  
**Christina** 6:14  
**chronic** 20:4; 22:23;  
24:1; 25:7; 69:25; 70:24;  
72:24; 73:18; 82:3, 6;  
85:11; 88:2, 4, 23; 173:1;  
175:24; 176:2; 213:11;  
215:5  
**chronically** 114:13;  
181:24  
**cigarette** 180:20  
**circulation** 180:15  
**circumferential** 42:8  
**circumstance** 137:25;  
138:9, 19  
**circumstances** 132:7;  
137:15; 203:12; 228:11  
**cisapride** 78:21; 79:11,  
21  
**cisepride** 198:2  
**claims** 9:22; 53:20;  
101:16, 18; 150:12  
**clarification** 159:19, 21  
**clarify** 237:20  
**class** 73:17; 128:12;  
145:21, 23, 25  
**classic** 70:23  
**classically** 176:1  
**classification** 13:5

**clear** 5:18; 38:16; 46:15;  
52:2; 72:25; 81:8; 85:13;  
88:18; 129:4; 130:8;  
136:20; 178:6; 185:25;  
186:1; 191:16; 197:21;  
237:7  
**clear-cut** 236:21  
**Clearly** 36:22; 37:16;  
39:22; 43:18; 45:7; 77:23,  
25; 84:25; 86:18; 139:22;  
140:17; 178:14; 189:14;  
197:23; 240:15  
**Clinic** 21:8; 158:3  
**clinical** 6:22, 24; 16:10;  
23:22; 34:8, 9; 36:3, 10,  
20; 37:3; 40:5, 9; 42:20;  
44:8; 47:19, 25; 49:21;  
50:9, 12, 16, 17, 23; 51:6;  
53:11, 12; 54:11; 55:10,  
22, 24; 56:4, 18, 19; 57:5;  
58:9; 66:10; 71:22; 77:21;  
80:25; 86:16, 23; 87:2;  
90:15; 91:5, 8; 112:4;  
126:25; 128:7; 129:7, 8,  
17; 138:12; 146:21;  
159:23, 23; 160:2; 164:20,  
22; 170:8, 13, 18; 174:16;  
189:21; 202:19  
**clinically** 24:13; 27:14;  
50:13; 71:8  
**clinicians** 176:19  
**close** 97:4; 164:22;  
180:17  
**closely** 146:1  
**closer** 215:16  
**cm** 36:21; 42:10  
**CME** 155:10  
**CMS-4** 160:1  
**CNS** 58:24  
**co** 58:1  
**Co-Chair** 7:21  
**co-medications** 117:24;  
119:11  
**co-morbidities** 153:3  
**coagulation** 57:25; 58:1;  
120:22  
**codes** 51:24; 52:3; 53:9;  
148:22; 150:13, 13  
**coding** 51:23  
**cofactor** 182:6; 188:9  
**cofactors** 181:25; 182:3  
**cohort** 22:2; 23:15, 21;  
24:6, 13, 20; 25:20, 21;  
26:7; 27:3; 51:6; 52:6;  
54:23; 150:24; 151:1, 4, 8,  
9, 10, 13, 14, 19, 20;  
153:16, 21; 183:1  
**cohorts** 23:23; 150:24;  
151:9, 13, 17  
**colectomy** 37:11; 97:3,  
9; 122:7; 123:3; 130:3;  
206:8  
**colitis** 16:7, 8; 33:10, 17,  
19, 23; 34:2; 39:1; 40:2, 5,  
12, 18; 41:14; 42:19, 22,  
25; 43:5, 7, 10, 15, 16, 17,  
18; 45:23; 46:13; 48:8;

50:1, 24; 51:16; 52:10, 17;  
53:10; 55:1, 15; 56:4;  
57:14; 59:21; 61:14; 63:8;  
66:18; 71:13, 16, 18;  
75:17; 77:12; 80:17;  
86:20, 23; 87:14; 90:25;  
95:19; 98:4; 103:12;  
104:2; 105:19; 116:13, 16,  
20, 22; 117:2, 7, 10;  
118:20; 119:1, 11, 15, 19,  
22, 22, 25; 120:1, 3, 4, 18,  
121:25; 122:1; 123:2, 17;  
129:17, 20; 130:2, 5;  
132:16; 146:3; 148:10, 12,  
20; 149:2; 156:23; 162:19;  
180:6; 188:19; 194:25;  
195:1, 3; 198:14, 22;  
202:23, 24; 203:1; 206:21;  
213:14; 240:25  
**collaboration** 52:25;  
55:5, 18  
**collaborative** 55:6;  
131:6  
**collaborators** 178:24  
**collate** 147:1  
**colleague** 200:22  
**colleagues** 21:7; 85:6  
**collected** 50:17  
**collecting** 178:18;  
240:19  
**collection** 240:18  
**College** 6:13  
**colon** 37:6, 8, 25; 38:23;  
39:2, 9; 41:9; 42:3, 4, 6, 8,  
9, 9; 43:22; 121:23; 122:5,  
7, 19, 25; 180:11, 13, 21;  
181:1; 182:12, 12; 200:23  
**colonic** 42:13, 14; 43:20;  
97:15; 123:15; 156:22;  
180:16  
**colonopathies** 116:12,  
12, 15, 22; 118:19  
**colonopathy** 121:3  
**colonoscopies** 43:4;  
195:7, 10  
**colonoscopy** 36:20, 20,  
23; 37:24; 38:25; 41:11;  
119:25; 120:3, 17; 195:11;  
198:25  
**colorectal** 7:23; 198:20  
**colostomy** 38:23; 97:9;  
122:6  
**column** 113:6  
**combination** 78:23;  
174:3  
**combined** 107:9  
**comfort** 79:23; 215:1  
**comfortable** 198:2  
**coming** 27:19, 23; 89:7;  
106:10; 206:10; 217:3;  
236:24; 238:16, 16  
**commensurate** 72:9  
**comment** 5:13; 79:3, 9;  
87:10; 94:2, 3; 98:25; 99:1;  
100:7, 18; 101:13; 104:11;  
143:6; 162:2, 24; 198:14;  
202:4, 22; 208:8, 20;

210:23; 241:6  
**commented** 185:4  
**comments** 5:5; 8:11;  
97:22; 164:3; 184:21, 22;  
185:6; 191:10; 193:2;  
198:12, 18; 203:5; 208:6;  
211:25; 216:23; 217:7;  
220:10; 224:7, 7, 25;  
234:23  
**commercial** 59:1  
**commit** 219:9  
**commitment** 47:6, 7;  
59:9; 95:9, 11  
**commitments** 175:19  
**committed** 47:14; 56:19  
**committee** 7:7; 8:13;  
12:10, 15, 21; 13:10;  
15:22; 19:9; 28:12; 33:21;  
43:11; 45:12; 46:23;  
58:22; 76:20, 22; 100:11;  
106:18, 20; 110:19; 116:6;  
118:13; 124:18; 129:3;  
133:4, 21; 134:5; 143:25;  
150:21; 154:15; 157:10;  
163:5; 164:4; 172:3;  
177:14, 23; 178:11;  
201:24; 208:4, 4; 209:17;  
210:2; 215:1; 216:24;  
222:17; 232:15, 20;  
233:24; 236:3; 241:23  
**committee's** 110:11;  
114:17; 115:23; 199:3  
**committees** 112:11  
**common** 71:19; 175:18;  
186:2  
**commonly** 31:21; 93:6  
**communicate** 14:7;  
59:15, 17, 19; 67:20, 24;  
72:4; 92:9; 98:15, 20, 24;  
105:16; 124:23; 128:10;  
130:20; 222:23  
**communicated** 125:13  
**communicates** 228:1  
**communicating** 50:4;  
62:23  
**communication** 8:5;  
17:23; 47:9; 48:14; 60:1, 5;  
61:11; 64:15, 21; 66:20;  
67:15, 25; 91:17; 92:4;  
98:8; 99:1; 100:4, 13;  
130:15  
**communications** 18:19;  
48:4; 53:25; 54:16; 58:14,  
17, 19; 59:7, 25; 60:11, 22;  
61:7, 17; 63:24; 67:8, 10,  
23; 68:2; 69:6; 104:13, 21,  
22; 105:9; 124:4; 130:22;  
231:7, 12  
**community** 10:5; 172:22;  
173:19, 23; 176:10, 19;  
193:11; 222:20, 22, 22  
**compact** 241:24  
**companies** 9:7; 92:2;  
98:23; 176:9; 219:5;  
228:21; 230:23  
**company** 47:14; 49:4;  
53:2; 91:16; 112:11;

149:3, 17; 155:9; 188:4;  
189:8, 11, 20; 207:4;  
209:11; 210:5; 215:21, 22;  
218:13; 219:9, 9; 226:15,  
16; 229:14; 230:19;  
232:18; 233:18; 234:3;  
240:15, 17; 241:22  
**company's** 210:11, 14  
**comparable** 16:13;  
21:12; 24:25; 26:11, 15;  
27:6; 70:15; 71:13; 86:10  
**comparative** 31:17;  
128:15; 159:25  
**comparator** 32:3; 160:6  
**comparators** 93:4, 5, 10  
**compare** 24:3, 13; 25:4;  
53:12; 72:23; 202:12;  
223:19  
**compared** 22:2, 8; 23:15,  
20; 24:7, 19, 20; 25:11, 19,  
24; 26:5, 19; 27:4, 11;  
31:20; 32:12, 22; 50:24;  
99:12; 154:2; 157:12;  
202:13  
**compares** 69:24  
**comparing** 26:13; 93:6  
**comparison** 27:11;  
157:16, 21, 24  
**comparisons** 25:17;  
52:20; 53:13; 157:18  
**compatible** 119:22  
**compelling** 186:6;  
187:12  
**compensated** 167:1  
**competency** 67:18  
**complain** 9:19; 19:20  
**complaining** 41:17  
**complaint** 89:8  
**complaints** 19:15, 21;  
21:22, 24; 38:11, 17  
**complete** 18:20; 64:7;  
149:3  
**completed** 32:5; 44:13;  
55:11, 25; 71:2  
**completely** 5:18; 228:20  
**completeness** 227:6  
**completing** 43:24  
**completion** 29:7; 38:21  
**complex** 10:8; 173:2;  
174:17  
**compliance** 11:2; 50:13;  
151:12, 24; 152:1  
**complicated** 9:20; 36:18;  
37:11; 40:25; 175:21;  
200:19; 201:1  
**complication** 24:10;  
37:17; 81:1; 82:11; 95:2;  
186:12; 193:5; 196:1;  
200:3, 8, 14, 24; 204:5;  
216:8; 218:7  
**complications** 17:19;  
34:18; 39:19, 21; 46:14;  
49:22; 50:22; 52:11, 15;  
54:25; 71:21, 21; 72:18;  
74:5; 77:10; 81:24; 82:5;  
94:13; 97:23, 24; 98:3, 6;

99:2, 10; 102:5; 103:19,  
20; 121:22; 130:6; 132:15;  
148:12; 165:12, 17;  
13; 178:13; 181:5;  
20, 21; 183:4; 184:5;  
185:15; 188:12, 13; 189:2,  
19; 192:14; 193:15;  
198:15, 16; 199:4, 7, 13,  
19, 25; 201:4, 15, 19;  
202:8, 14, 18, 19; 206:8,  
24; 218:12; 238:15; 240:1,  
3, 9; 241:11  
**component** 14:6, 9;  
26:24; 27:1, 2, 4, 6, 10, 13;  
54:2; 57:11; 105:11;  
189:6; 191:2  
**components** 13:24;  
47:7; 48:25; 59:8; 62:17;  
65:5; 69:7; 105:11, 12  
**composite** 71:2; 206:4;  
230:6  
**comprehension** 68:5,  
11, 17; 72:5  
**comprehensive** 13:23;  
104:12; 105:20; 139:12,  
19  
**comprise** 17:1  
**computer** 63:16; 135:3;  
220:3  
**computerized** 145:10  
**conceivable** 72:7  
**cept** 16:24; 189:25;  
11, 21  
**concepts** 11:25; 212:4, 5  
**concern** 86:13, 14;  
94:14; 97:20; 135:7;  
137:8; 140:7; 142:4, 12;  
147:21; 162:18; 190:12;  
196:14; 198:22; 199:16;  
229:3; 231:4; 233:8;  
238:20  
**concerned** 10:3; 86:13;  
130:1; 146:3; 181:17;  
211:6; 220:21; 227:18  
**concerning** 227:21  
**concerns** 94:4; 147:21;  
155:7; 176:20; 220:24;  
226:9, 19  
**concert** 134:20  
**conclude** 16:1, 11; 71:7  
**concludes** 76:9  
**concluding** 18:21  
**conclusion** 17:14; 43:7;  
69:19; 70:8; 132:23;  
142:10; 151:24  
**conclusions** 33:1; 39:16;  
43:14; 45:15; 46:6; 71:12;  
114:5; 115:1; 143:23;  
155:5  
**comitant** 128:6;  
130:15  
**concrete** 175:5  
**condition** 14:20; 38:15,  
25; 41:15; 67:5; 74:15;  
132:9; 140:14; 168:9;  
173:1; 175:12; 176:15;  
190:16; 200:17; 203:11;

216:7; 229:15  
**conditions** 9:1; 24:2, 21;  
51:18; 57:5; 79:14, 16;  
114:21; 132:6, 11; 147:3;  
152:17, 21; 206:25;  
214:16; 220:4; 234:15  
**conduct** 66:24; 67:14;  
69:3; 155:18  
**conducted** 28:23, 25;  
31:16; 49:16; 52:24; 53:6;  
54:17; 55:21; 57:21;  
68:19, 24; 144:5; 150:23  
**conducting** 55:1; 56:19  
**confer** 85:5  
**confidence** 10:13;  
103:16  
**confident** 60:21; 69:6  
**confidential** 5:17, 23  
**confines** 189:16  
**confirm** 51:25  
**confirmation** 146:8  
**confirmatory** 147:15  
**confirmed** 120:1, 4  
**confirms** 175:4  
**conflict** 4:9, 16  
**confound** 146:16  
**confounders** 147:4  
**confounding** 45:8; 240:4  
**confused** 154:19  
**confusing** 199:21;  
238:22  
**congestive** 24:22; 118:5  
**conglomerate** 217:1  
**Congress** 224:7  
**congressionally** 134:21  
**connection** 220:18  
**Conner** 169:14, 15, 15;  
171:15, 17, 20, 23; 172:1  
**consecutive** 35:16, 19  
**consensus** 230:3  
**consent** 101:9; 102:1, 4;  
240:6  
**consequence** 91:10;  
127:7  
**consequences** 174:18;  
204:1  
**conservative** 89:23  
**consider** 58:16; 100:14;  
143:25; 159:12; 174:21;  
194:14  
**consideration** 5:24;  
17:7; 143:2; 145:22;  
208:10; 238:25  
**considerations** 143:24;  
154:14  
**considered** 54:3, 5, 13;  
127:19; 133:1; 142:6;  
231:18  
**considers** 85:21  
**consist** 118:8  
**consisted** 118:9; 120:21;  
121:22; 122:4  
**consistency** 19:18; 31:8;  
70:9; 81:18; 82:25; 83:2, 7;

141:23; 161:14  
**consistent** 20:19, 22;  
41:13; 49:9; 69:2; 72:21;  
73:5; 112:9; 138:24;  
139:6, 6; 173:23  
**consistently** 139:13  
**consisting** 19:15  
**consists** 19:17; 55:7;  
100:20  
**Consortium** 7:22;  
153:14  
**constantly** 89:7; 99:20;  
168:1  
**constipated** 35:1, 3;  
36:22; 49:23; 81:19, 21;  
82:12, 13, 23; 83:6, 9;  
86:8; 88:5, 6, 7, 9; 89:22,  
23, 24; 98:6; 100:22;  
158:4; 165:10, 16, 24;  
166:1, 9; 216:17  
**constipation** 16:15;  
17:3, 19; 33:10, 20; 34:16,  
17, 18, 22, 24; 35:2, 4, 6,  
13; 36:1, 13, 15, 25; 37:17,  
18, 23; 38:1, 9, 12; 39:13,  
17, 17, 19, 22, 24; 45:23;  
46:14; 48:7; 49:21, 22;  
50:1, 22; 52:12, 16; 53:20;  
54:25; 56:21, 24; 59:18,  
19; 61:13; 63:7, 14; 65:13;  
66:16; 71:21; 72:17; 74:1,  
2, 5; 75:17; 77:17, 18, 23;  
78:7, 15; 80:17, 23; 81:1,  
6, 15, 25; 82:3, 6, 10, 11,  
18; 83:13, 16, 17, 17, 22;  
84:1, 4, 10, 11, 15, 18;  
85:11, 13, 15, 18, 20, 21;  
86:1, 11, 19, 21, 24; 87:8,  
15, 18; 88:2, 3, 4, 10, 24;  
89:5, 17, 18; 94:6, 8, 10,  
11, 12, 15; 97:2; 98:5;  
99:9, 10; 100:20; 103:19;  
104:1; 105:18; 109:21;  
116:13, 19, 21; 122:10, 12,  
16; 123:17; 128:20, 20, 22;  
129:4, 12; 130:8; 132:15;  
137:23; 146:2; 148:10, 12,  
20, 25; 149:5, 8; 155:15;  
156:23; 157:14; 160:8;  
165:5, 6, 11; 171:17;  
174:12; 178:14, 21; 179:2,  
3; 183:11, 14; 184:5, 11;  
187:25, 25; 189:4, 5;  
194:22; 198:16, 16; 199:2,  
5, 7, 17, 25; 200:1, 8, 12,  
15, 16, 18, 21, 24; 201:4,  
14; 202:8; 206:21; 210:7;  
213:12, 12, 16, 25; 214:2,  
4, 23, 24, 25; 215:6, 8, 13,  
22; 216:1, 5, 7, 10, 10, 12,  
13, 16; 221:9, 11; 229:17;  
235:16, 16, 22; 237:24;  
240:10  
**constipation-**  
**associated** 116:15;  
117:6; 121:3  
**constipation-diarrhea**  
39:6  
**constituting** 28:20

**constraints** 147:17, 18  
**construct** 22:14  
**consult** 50:25  
**consultant** 8:2; 180:6;  
181:4; 184:20; 224:22;  
229:3  
**consultants** 76:10, 14;  
232:20  
**consultation** 54:4  
**consulted** 49:11  
**Consumer** 7:21; 131:16;  
132:1; 139:10; 217:25;  
232:4; 235:9  
**consumers** 6:17; 7:21;  
130:24; 219:18  
**contact** 137:24  
**contacted** 40:21; 42:22;  
174:14  
**contacting** 42:20  
**contain** 62:4; 63:4, 13;  
64:18; 67:7  
**contained** 14:2; 64:4  
**container** 124:13; 141:14  
**containers** 136:25  
**contamination** 97:16  
**contemporary** 13:22;  
52:22  
**contend** 174:11  
**content** 135:22; 136:17;  
139:4; 142:13; 223:8  
**context** 73:4; 80:22; 82:1;  
99:20; 100:3; 206:15  
**continually** 175:9  
**continue** 86:9; 114:9;  
138:3; 170:13; 176:21;  
227:14  
**continued** 14:4; 17:1;  
48:21; 72:2; 188:2  
**continues** 204:17  
**continuous** 87:24;  
212:14  
**contraceptive** 58:2  
**contraceptives** 90:16;  
135:23; 181:8, 13  
**contractile** 96:6  
**contraction** 96:7  
**contractions** 96:9  
**contraindicate** 88:1, 5  
**contraindicated** 82:2;  
128:9; 153:2, 24; 154:1;  
216:18  
**contraindication** 74:23;  
75:19; 152:19; 155:15;  
214:1, 2  
**contraindications**  
79:13, 18; 88:1; 126:5;  
131:19; 140:15, 16;  
152:16; 153:1; 154:9;  
155:13; 213:10; 214:22;  
215:5; 216:12; 219:25;  
234:11, 15; 235:15, 20, 23;  
236:5  
**contrast** 38:22; 125:18;  
128:21  
**contribute** 146:14, 16;

167:10  
**contributed** 79:14  
**contribution** 55:5  
**control** 22:2; 51:7, 8;  
55:4; 56:3; 90:1; 161:2;  
170:10; 171:9, 10; 179:5,  
11, 19; 180:1; 223:19  
**controlled** 231:2; 232:19  
**convening** 106:19  
**convey** 61:11  
**Cook** 166:19, 20; 168:14,  
17, 20, 25; 169:3, 5, 8, 13  
**COPD** 118:6  
**Copies** 4:19  
**corollary** 159:13  
**coronary** 74:18  
**corporate** 59:9  
**correctly** 102:21; 201:7;  
237:3  
**correlate** 83:7  
**cost** 10:23, 24, 24; 145:12  
**costs** 21:1, 2, 9, 12, 18;  
22:3; 27:20, 21; 28:6  
**counseling** 101:1, 3, 6,  
8; 102:6; 134:14  
**count** 41:6  
**counting** 201:3  
**country** 20:1; 24:1  
**County** 21:10, 16; 55:24;  
98:13  
**couple** 94:3; 97:22;  
149:21; 183:15; 184:21;  
214:6; 224:25  
**coupled** 17:22; 131:24;  
157:5  
**course** 5:7; 8:22; 13:25;  
31:10; 35:4, 18, 23; 37:11;  
38:21; 40:23; 41:25;  
43:24; 44:8; 48:20; 81:15;  
84:6; 87:11; 96:6; 122:23;  
145:22; 159:24; 165:24;  
166:7; 178:23; 186:19;  
187:19; 193:13  
**courses** 155:10  
**cover** 188:23  
**coverage** 53:4, 5  
**covered** 88:13  
**COX** 70:22  
**CPT** 150:13  
**cramping** 41:5; 121:17  
**crave** 175:17  
**create** 10:14  
**creates** 140:8  
**creative** 230:22  
**crisis** 10:12  
**criteria** 25:9, 9; 81:3;  
82:23; 87:21; 89:20;  
110:20; 120:10; 127:17;  
144:12; 173:6, 11, 17, 21;  
189:2; 190:14; 197:16, 17,  
18; 212:17, 25; 215:24  
**critical** 16:18; 138:11;  
141:5; 221:19; 238:8  
**critically** 54:14



**Crohn's** 187:2; 189:4  
**cross-sectional** 153:21  
**crosses** 49:3  
**crucial** 8:24  
**crypts** 120:23, 25  
**CT** 38:12, 23; 39:8; 41:8;  
42:2; 119:20; 120:13;  
186:3  
**cultivate** 10:17  
**cultural** 57:16  
**culture** 10:14, 17; 95:3  
**cultured** 94:20  
**curative** 14:21; 115:2;  
123:8; 138:6; 157:1  
**cure** 167:5  
**current** 5:11; 45:3; 49:17;  
54:10; 60:20; 63:21; 64:1;  
86:19; 177:17; 187:25;  
215:8; 216:13; 225:14, 18  
**currently** 18:1; 56:2;  
57:1, 23; 88:5, 6; 99:7;  
108:18; 112:11; 125:9;  
142:23; 145:14; 223:25;  
226:16  
**curves** 158:24  
**customer** 66:3  
**cut** 34:5  
**cut-off** 34:11; 36:2; 40:8,  
22; 117:5; 129:21  
**cytochrome** 153:1

**D**

**dad** 170:20  
**daily** 20:6; 82:20, 21;  
89:15  
**danger** 102:23  
**dangerous** 92:7, 17;  
99:13  
**dangers** 74:24  
**data** 9:5; 14:2, 16; 16:1;  
17:10, 14, 16, 20; 18:15;  
23:6, 16, 21, 22; 24:20;  
25:6, 11, 19, 21; 27:5, 12;  
30:12; 33:7; 42:23; 46:17;  
49:17; 50:17; 51:10;  
54:12, 21; 58:14; 69:4, 23,  
25; 70:7, 8; 71:1, 6, 17;  
72:12; 76:3; 82:25; 86:12,  
15; 92:9; 93:4; 96:18;  
99:11; 100:19; 110:23;  
111:2, 10, 17, 19, 20, 23,  
24, 25; 112:2, 3, 10;  
113:19; 115:11, 15; 117:5;  
127:1; 128:14; 130:10;  
150:20; 157:19; 159:14,  
16; 165:18; 166:18;  
174:25; 175:1, 5; 178:12,  
17; 179:25; 181:6; 184:3,  
6; 195:11, 13; 203:1;  
204:25; 207:5; 210:25;  
221:17; 224:19; 227:25;  
228:8; 231:19; 238:22;  
240:20  
**database** 36:4; 37:21;  
40:16; 43:2; 44:5, 16;

45:20; 48:18; 52:25; 53:3,  
3; 55:2, 7, 9; 78:12; 87:6;  
89:15; 103:10, 21; 129:18;  
145:9; 150:24; 153:5  
**databases** 51:12, 13;  
101:14, 17, 17, 21; 102:25;  
103:2, 3, 5, 11, 25; 148:22;  
153:6; 155:19; 156:1;  
183:19; 234:13; 241:17  
**date** 34:6, 11; 36:2; 40:8;  
129:21  
**dating** 55:8  
**day** 89:16; 117:21;  
121:14; 167:12; 169:21;  
171:4; 174:14; 175:20;  
185:21; 212:19  
**days** 22:8, 8; 29:14;  
30:21; 35:6, 7, 16, 19;  
36:12, 24; 37:22; 38:3, 4,  
9, 10, 15, 20, 21; 39:7;  
77:21, 24; 83:18, 18;  
117:20, 22; 119:17, 17;  
120:13; 121:13, 14, 15, 15;  
165:14; 168:25; 186:21;  
215:9, 12  
**deal** 214:11; 221:16  
**dealing** 87:3, 9  
**deals** 149:25  
**dear** 60:11, 23; 80:9;  
130:17; 150:5; 151:1, 2, 3;  
152:14, 22; 153:7, 9, 18,  
25; 154:8, 16; 155:4;  
158:7, 8; 211:1  
**death** 100:2; 126:24;  
130:3; 205:17, 19, 22, 25;  
206:10, 15  
**deaths** 11:15; 36:5;  
39:23; 40:14, 20; 73:11,  
14; 74:17, 18; 97:23;  
99:15; 205:21; 206:15  
**debatable** 191:6  
**debate** 227:15  
**debates** 187:21  
**decade** 223:4  
**decades** 13:12; 55:23  
**December** 49:2; 54:17,  
22; 151:2; 152:14  
**dechallenge** 146:9  
**decide** 80:13; 101:3;  
195:21; 196:11; 198:3  
**decided** 103:25; 238:25  
**deciding** 241:18  
**decision** 138:2; 170:9;  
224:8  
**decision-making** 8:3  
**decisions** 92:19  
**decompaction** 184:10  
**decompressed** 38:24  
**decompression** 122:6,  
24  
**decrease** 196:23;  
201:21; 202:17  
**decreased** 70:1; 128:1;  
154:3; 199:18  
**decreasing** 196:18, 25;  
235:23

**dedicated** 48:9  
**dedication** 8:21  
**deeper** 120:25  
**defect** 42:11  
**defer** 91:4; 95:11; 188:20  
**deferrals** 227:24  
**define** 20:24; 22:19;  
52:14, 16; 54:3; 81:12;  
216:3, 6  
**defined** 32:17; 84:23;  
93:16; 103:11, 18; 105:25;  
106:4; 215:10; 235:17;  
237:16  
**defines** 124:14  
**defining** 47:8  
**definite** 179:17  
**definitely** 170:9; 206:23;  
229:13  
**definition** 47:24; 56:17;  
57:11; 58:5; 81:4, 8, 14,  
15; 87:22; 100:19; 106:7;  
119:3; 146:20; 180:7;  
183:10, 13; 199:11;  
214:24; 215:18; 216:4  
**definitions** 81:16; 88:18;  
89:13, 20  
**definitively** 81:12  
**degree** 30:13  
**degrees** 120:14  
**deliberate** 12:13  
**deliberations** 15:24  
**deliver** 48:5  
**delivery** 153:12; 155:24  
**delving** 11:7  
**demand** 228:24  
**demographics** 85:7  
**demonstrate** 59:8; 76:4  
**demonstrated** 111:15  
**demonstrates** 47:5;  
175:1  
**demonstrating** 111:10;  
112:1; 159:15  
**demonstration** 234:1  
**denominator** 76:25;  
199:7  
**dense** 37:4  
**densely** 37:7  
**department** 62:12; 66:11  
**depend** 168:10  
**dependent** 138:14  
**depending** 82:13;  
175:19; 195:9  
**Depends** 168:1, 2  
**depicts** 151:12  
**depressed** 24:14; 27:14  
**depression** 23:22; 24:2;  
26:19; 27:5; 118:4; 161:6  
**depth** 50:17; 51:10; 56:9  
**derived** 14:2  
**describe** 16:17; 47:2;  
48:10; 50:7; 52:5, 18;  
54:10; 55:15; 61:6, 21;  
65:5, 24; 68:1; 126:9, 10,  
12; 152:24; 213:17

**described** 9:11, 12; 14:7;  
16:24; 54:20; 58:8; 60:25;  
62:15; 64:9, 21; 65:1, 10;  
69:8; 74:12; 118:12;  
119:23; 120:23; 121:1;  
147:3; 152:15; 181:22;  
200:15  
**describes** 62:7; 74:22;  
212:17  
**describing** 62:2  
**descried** 18:16  
**description** 18:19;  
105:5; 119:24; 140:7  
**deserving** 15:2  
**design** 17:9; 31:18; 51:6,  
8; 52:9, 11  
**designed** 50:20; 58:6;  
61:11; 65:12; 66:25;  
67:24; 137:7  
**desire** 147:18  
**desired** 107:19, 19;  
108:12; 109:11; 149:19;  
207:14  
**Desk** 9:5  
**Despite** 191:22; 241:17  
**detail** 16:17; 60:12;  
61:22; 103:22; 104:5;  
118:12; 125:3, 17; 168:14,  
16; 225:11  
**detailed** 36:8; 105:4;  
133:3  
**details** 185:3  
**detect** 145:4  
**detected** 145:5  
**detection** 48:7  
**deteriorated** 37:3  
**deteriorates** 204:18  
**determination** 127:15  
**determine** 14:11; 42:18;  
47:11; 80:19; 101:10;  
138:13; 155:3, 5, 12  
**determined** 4:13; 9:7, 9;  
58:3; 138:21  
**determining** 93:2;  
228:10  
**devastated** 170:24  
**devastating** 174:18;  
175:15  
**develop** 11:21; 47:15;  
53:7; 77:23; 98:15, 20, 24;  
103:9; 146:20, 22, 25;  
149:4; 181:11; 183:5;  
227:9  
**developed** 36:10, 13, 25;  
37:14, 23; 38:9; 39:7; 47:5;  
61:7; 76:5; 77:18, 18;  
78:15; 83:17; 146:23;  
149:7; 234:5  
**developing** 49:10; 179:2,  
19; 196:15  
**development** 12:1; 34:9,  
9; 36:3, 10; 40:5, 9; 41:13;  
53:8; 57:23; 77:17; 86:23;  
180:14  
**diabetes** 24:2, 10; 26:12;  
27:7; 70:2

**diabetics** 23:21; 24:4, 7,  
9; 26:5  
**diagnose** 204:7  
**diagnosed** 167:5  
**diagnoses** 97:20, 21;  
149:6  
**diagnosing** 173:24;  
190:15  
**diagnosis** 19:14; 20:14,  
18, 21; 38:14, 18; 41:21;  
52:1; 110:3, 5, 7, 14, 16;  
120:2; 132:13, 14; 146:8,  
21; 147:15; 148:24;  
150:13; 173:7, 11, 13, 25;  
174:5, 7; 190:1, 3, 17, 22;  
204:5; 212:17; 240:24  
**diagnostic** 51:24; 52:3;  
120:10; 173:4; 190:14;  
212:25  
**dial** 220:22  
**dialed** 220:16  
**dialing** 221:18  
**dialogue** 16:23  
**dialysis-dependent**  
25:14; 26:17  
**diameter** 39:2  
**diarrhea** 8:19; 19:18;  
32:6; 41:17, 23; 59:15;  
71:9; 77:7, 11; 80:15; 81:5,  
14; 83:1; 84:4, 10, 13, 18;  
86:1, 5; 87:20, 22, 25;  
89:5, 8, 10, 19; 94:6, 8, 15,  
100:20, 22; 106:24;  
108:17; 109:21; 120:11;  
165:2; 168:25; 169:21;  
170:10; 174:11; 206:16;  
212:12, 15, 24; 213:3, 5,  
25; 214:2, 15  
**diarrhea-predominant**  
13:3; 15:5; 29:3; 31:10;  
33:3; 46:10; 70:11; 84:7;  
85:23; 109:15; 110:5, 14;  
111:11; 112:3, 16; 114:6;  
212:12, 18  
**diarrhea-type** 119:6  
**diary** 65:11, 11  
**Dick** 6:18; 7:13  
**dictated** 50:14  
**dicyclamine** 160:7, 9  
**die** 98:1  
**died** 99:24  
**dietary** 20:9  
**differ** 157:22; 173:9  
**difference** 71:3; 93:8, 9,  
96:3, 10; 112:22, 23;  
180:15; 181:19; 193:5;  
205:25  
**differences** 155:22;  
186:23; 191:16; 197:22  
**different** 21:19; 23:1, 10,  
25; 24:1; 54:5; 57:4; 83:1,  
87:4, 8; 90:18; 94:5, 7;  
96:17; 100:14, 15; 135:2,  
21; 153:11, 11; 155:24;  
175:8; 181:24; 187:9;  
217:15, 19; 218:19; 220:  
228:2; 230:10; 231:3;



238:15  
evaluated 16:10; 21:3, 8;  
22:3, 4; 25:7; 31:2; 32:9;  
3, 20; 57:7; 162:10;  
59; 227:10  
evaluates 23:11  
evaluating 11:2; 103:7;  
107:18; 149:18; 231:2  
Evaluation 4:15; 6:7;  
10:18; 32:20; 47:11;  
48:13; 49:1; 51:16; 54:2;  
58:12; 59:8; 68:1; 69:7;  
72:5; 73:12; 107:6; 22;  
147:16; 192:5; 224:12;  
233:14; 234:8, 18; 235:18;  
237:8  
evaluations 68:10  
Evelyn 108:10; 143:12  
even 4:10; 74:7; 85:13;  
90:9; 98:24; 100:8;  
101:11; 103:14; 110:25;  
136:10; 155:10; 159:6;  
162:19; 163:3; 170:1, 5;  
173:8; 174:18; 180:21;  
181:12; 190:9; 192:25;  
199:20, 22; 200:5; 206:1;  
208:25; 210:19; 218:24;  
223:11; 224:13; 227:5;  
231:18  
event 4:4, 22; 9:12;  
34:15, 23; 39:18; 43:23;  
44:2; 77:14; 117:20;  
112; 129:5, 12, 24;  
132; 144:23; 145:9, 21;  
146:7, 12, 14; 147:9, 10,  
10; 179:25, 25; 195:16;  
197:13; 202:25; 206:17;  
235:21  
events 9:10; 10:23;  
11:12, 16, 19; 16:12;  
17:17; 36:1, 2, 3; 37:12;  
41:1; 46:4; 47:9; 48:1;  
49:25; 50:15; 52:2, 19;  
56:7, 14; 57:9; 73:21, 21;  
74:4, 8, 11, 18, 20; 75:2, 7;  
87:14; 108:4; 116:1, 3, 8,  
10, 11; 117:13; 118:21;  
124:9; 126:6; 128:20;  
145:2, 14, 20; 147:14, 16;  
150:4; 179:20; 180:2;  
194:17, 20; 235:23  
eventually 36:23; 134:2  
everybody 8:9; 178:3, 5;  
207:25; 224:8  
everybody's 78:22  
everyday 170:12  
everyone 101:7; 189:6;  
208:14  
everyone's 11:20  
evidence 15:13; 16:2;  
20; 58:13; 93:7;  
5:16; 136:22; 179:7, 9;  
180:25; 186:13; 196:18;  
214:8; 225:9  
evidence-based 5:7  
evident 185:1  
evolving 10:19  
exact 235:10

exactly 87:12; 163:8;  
199:16; 218:23; 239:9  
examined 187:15  
example 10:22; 22:23;  
72:10; 73:25; 74:10;  
105:5; 109:16; 111:13;  
127:11, 20; 128:2, 4, 11;  
131:24; 132:12; 133:8;  
137:20; 144:20; 145:23;  
146:2; 155:20; 156:15;  
162:11; 191:18; 200:25;  
213:22; 220:3, 24; 239:3  
examples 73:6; 75:8;  
92:6; 99:5, 12; 142:19;  
177:16; 218:19, 21  
Excellence 49:14  
excellent 49:7; 160:22;  
161:2  
except 141:23  
exception 30:7  
exceptions 4:17  
exclude 4:25; 188:5  
excluded 115:8, 12, 14  
excluding 62:6  
exclusion 5:1; 144:12;  
173:13  
exclusive 213:2  
exclusively 28:25  
executive 4:5; 7:6; 8:6;  
171:6  
exemplify 188:25  
exempt 141:21  
exemptions 227:24  
exercised 210:12  
exertion 74:18, 24  
existence 55:10  
existing 13:7; 51:12;  
56:3; 64:3; 65:8; 132:5, 8  
exists 9:8; 172:6  
expand 75:19; 144:19, 19  
expanded 57:7; 189:22  
expands 144:18  
expect 91:10; 95:2;  
157:15; 228:21; 231:13  
expectation 137:10  
expecting 233:21  
expenses 164:17;  
169:16  
experience 43:12; 47:17;  
54:10; 56:8; 57:4, 7; 58:8,  
9; 101:15; 109:4; 132:13;  
136:6; 156:13; 164:25;  
172:7; 174:16; 175:10;  
194:8; 234:22  
experienced 112:5;  
119:20; 122:12; 131:14  
experiences 109:7;  
156:16  
experiencing 114:14;  
213:16  
experiment 95:9, 13  
expert 43:9; 45:13;  
76:10, 13; 95:16; 188:21  
expertise 12:1; 76:15;  
232:25

experts 10:16; 49:11;  
54:5  
expiration 124:16  
explain 111:9  
explained 19:21  
explaining 129:24  
Exploratory 42:5  
explore 48:1; 55:4, 15;  
84:24  
explored 104:5  
expose 204:22  
exposed 34:8, 10; 40:6,  
11; 58:10; 110:17; 114:13  
exposure 147:3  
exposures 40:8  
express 175:13  
expressed 112:6  
expression 175:18  
extension 125:10  
extensive 47:24; 49:16;  
55:1; 58:6; 67:23; 71:25  
extent 90:24  
extracted 73:17  
extrapolate 148:6;  
160:19  
extrapolated 21:14  
extremely 202:25; 206:1;  
219:5  
eye 188:21

**F**

face-to-face 33:14; 67:15  
facet 223:9  
facilitate 173:6  
facilitates 173:25  
fact 91:13; 114:10; 136:7,  
19; 141:6; 149:4; 183:5;  
185:23; 186:22; 191:21;  
203:16; 210:17; 227:24;  
233:20; 234:13; 235:19  
factor 149:1, 8; 180:14,  
22, 25; 181:11; 186:17;  
201:9; 240:4  
factors 45:8; 48:1; 50:15;  
51:2, 7; 52:15, 17; 55:5,  
16; 56:6, 7; 58:1; 79:13;  
87:13; 111:13; 113:6, 10,  
11, 15; 114:8, 11; 120:6, 7;  
124:9; 129:25; 145:17;  
147:4; 173:12; 178:18;  
179:16; 181:14, 20; 182:9,  
19, 19, 22; 183:4, 8, 24;  
186:20; 188:1; 189:20;  
206:18; 237:25  
fail 114:18  
failure 24:22; 45:9; 118:6,  
6; 122:2; 150:3, 5; 173:22;  
204:2  
fairly 90:24; 135:6; 214:4  
fairness 5:11  
fall 25:3; 27:24; 106:7  
false 114:9  
familiar 173:18, 19, 20,

21  
familiarity 173:16  
family 60:3; 100:16;  
175:11; 177:25  
far 85:9; 99:8; 130:2;  
135:12; 183:2; 184:11;  
192:12; 199:1; 219:18;  
233:9; 241:8  
fashion 138:18  
fast 89:20  
fastest 65:3  
fatal 74:11, 20; 75:2, 7  
fatigue 154:17  
favor 192:18  
favorable 76:4  
favoring 71:4  
favorite 204:21  
FDA 4:24; 6:7; 7:21; 8:22;  
9:5, 25; 10:3, 9; 11:3, 17;  
12:10; 13:6, 14; 14:19, 21,  
22; 15:3, 20; 16:4, 9, 24;  
17:18; 33:13, 18, 24; 34:1,  
6; 40:21; 61:4; 64:15;  
72:13, 16, 21; 74:21, 25;  
75:5, 11; 79:12, 24; 80:11;  
91:25; 92:2; 93:2; 95:10,  
11, 12; 101:23; 106:2, 5,  
13, 15, 18, 23; 107:1, 16,  
25; 112:8; 123:23; 125:18;  
126:25; 127:15; 130:1, 16,  
19; 132:7, 8, 10, 20;  
134:25; 135:15, 17; 136:2,  
13, 15, 19; 137:5, 16;  
138:21; 141:21; 143:9;  
147:13, 20; 155:2; 156:11;  
161:18, 22; 190:24; 191:2;  
202:5; 219:8; 223:5;  
224:23; 225:2; 233:19  
FDA's 4:20; 5:3; 8:24;  
16:21; 17:25; 70:5; 74:12;  
79:4; 107:5; 111:19; 143:7  
fear 147:18  
fearful 147:20  
feasibility 155:15  
feasible 149:2  
feature 73:2  
February 11:18; 13:9;  
106:25; 207:3  
fecal 121:17, 18; 122:11,  
14; 174:13  
feedback 166:3  
feel 92:6; 104:5; 160:5;  
161:20; 165:2; 175:13;  
181:4; 198:2; 228:5;  
238:19  
feeling 97:24; 210:19;  
212:21  
feels 142:6; 208:4  
felt 32:13; 79:22; 159:7;  
170:12; 213:6  
female 29:1; 31:18; 32:6;  
33:3; 36:12, 19; 37:22;  
38:2, 8; 39:4; 41:3; 46:10;  
70:10; 97:11; 119:5;  
121:11  
females 20:2; 84:7;

117:18  
ferret 87:12  
Ferry 4:18; 6:12, 12;  
15:21; 78:17, 18; 80:2;  
194:5; 236:17, 18  
fetuses 141:1  
fever 41:6; 121:19  
few 48:10; 119:4; 144:5;  
165:14; 170:11; 184:24;  
217:12  
fewer 185:1  
fiber 20:10  
field 76:15; 92:1; 159:6;  
197:19; 231:8  
fields 49:11  
fifth 136:5  
fifty 192:25; 193:9, 12  
filed 13:4  
fill 55:16  
filled 225:5  
final 61:3; 74:10; 106:9;  
171:5  
finalized 64:14  
finalizing 65:4  
Finally 31:8; 97:5;  
107:15; 108:13; 112:25;  
115:21; 122:22; 132:18;  
141:2; 157:2; 171:3  
financial 4:24; 5:12;  
164:14  
find 184:11; 194:17;  
228:6; 235:18; 237:15;  
241:9, 15  
finding 71:5; 110:19;  
130:4; 142:13; 236:4  
findings 19:22; 21:15;  
120:21; 146:1; 147:19;  
155:25  
fine 11:3; 134:2; 210:3;  
212:2; 228:17  
finish 123:6; 143:23  
finished 12:13; 25:2  
firm 5:8, 12  
firms 4:14, 23  
first 13:11, 24; 15:25;  
30:9, 23; 31:4; 34:15;  
36:11; 37:21; 47:23; 49:1;  
53:7; 54:16; 57:14; 60:22;  
77:23, 25; 80:14; 82:22;  
84:2; 87:19; 90:6; 101:20;  
107:6; 109:2, 10; 117:9,  
21; 118:11, 12; 119:7;  
125:3; 134:17, 19; 135:16,  
18; 139:7; 140:4; 149:25;  
150:2, 20, 25; 152:12;  
153:12; 158:2; 161:15;  
164:12; 177:12, 17;  
179:18; 185:4; 186:14;  
190:17; 193:23, 24; 204:2;  
207:9, 24; 216:24; 221:6;  
222:9; 225:1  
first-line 128:13  
Firstly 64:2  
Fisher 76:16; 229:2, 2  
Fishman 57:21

fit 215:13  
fits 225:24  
Five 21:7; 54:19; 80:24;  
87:6, 9; 137:11; 143:8;  
212:10; 217:20, 22;  
218:21; 224:1  
fix 6:1  
fixed 233:5  
flag 181:9; 187:8  
flags 63:16; 201:20  
flashing 219:17  
flatten 158:24  
flex 162:22; 163:1  
flexibility 141:23; 226:18  
flexible 162:21; 198:23  
flexure 41:10, 11; 119:21;  
162:24  
Florence 6:6; 12:6; 79:9  
Florida 170:19  
flow 57:18; 96:1, 2, 12  
fluoroquinolones  
145:23  
fly 168:6  
flying 170:19  
focal 120:22  
focus 15:20; 16:18; 19:1;  
33:15, 24; 52:10; 90:20;  
133:24; 198:13; 217:12  
focused 137:21  
focusing 13:23; 124:17  
fold 45:1  
folks 145:3  
follow 54:16; 92:12;  
98:23; 103:23, 24; 139:18;  
151:20; 162:25; 165:22;  
184:2; 217:6; 219:2;  
226:16  
follow-up 29:8; 38:25;  
104:10; 161:6; 189:18  
followed 9:21; 12:9; 29:5;  
55:23; 107:22; 108:2;  
188:16; 211:4  
following 4:8, 16; 13:9;  
29:7, 14; 32:12; 36:12, 24;  
37:22; 38:2; 40:25; 41:2;  
42:15; 62:25; 71:12; 73:6;  
76:13; 111:17; 125:2;  
140:12; 219:13  
follows 62:3  
Food 8:14; 47:14; 52:8;  
57:2; 58:22; 170:2, 22;  
175:17  
forbid 177:10  
force 131:8; 222:10;  
224:14, 15  
foreign-speaking  
222:21  
form 13:3; 15:6; 71:9, 15;  
87:21; 104:15; 111:19;  
212:20; 240:7  
format 106:1; 111:20;  
135:21; 136:17, 19;  
142:12; 155:6; 223:8;  
226:14, 16, 21; 228:2, 4  
formation 101:24

formats 100:14  
forms 124:19  
formulated 174:2  
forth 149:12; 155:25  
fortunate 167:13; 176:18  
fortunately 219:3  
Forty 111:10; 172:14  
forum 163:9; 164:3  
forward 8:16; 28:5;  
93:20; 112:9; 176:6; 242:4  
found 21:10, 20; 22:5;  
23:16; 24:3; 74:3; 111:20;  
154:7; 185:8; 217:19  
foundation 47:8; 217:16  
founder 172:18  
four 68:25; 89:25; 159:2;  
161:20; 167:12; 177:5, 9;  
179:10; 186:18; 187:19;  
215:9, 12; 218:9  
four-week 93:17; 161:22  
four-year 23:24  
fourth 30:2; 161:13  
frame 15:16; 80:23;  
177:2; 183:15  
framework 75:9  
Francis 6:20  
Francisco 7:24  
frankly 185:5; 216:6  
free 62:12  
Freedom 4:20; 219:21;  
230:20  
frequency 16:12; 19:19;  
31:3; 33:16; 42:18; 43:13,  
15; 46:12; 50:21, 23;  
56:14; 69:12; 71:14;  
81:17; 82:24; 83:2, 7, 11;  
127:4; 128:1; 129:23;  
161:14; 212:16, 19  
frequent 34:22; 39:17;  
72:13; 181:10  
frequently 43:8; 62:10;  
98:7; 203:2; 222:3  
friable 120:18  
friends 166:2  
front 142:15; 223:10;  
230:8; 237:8, 16  
frustrations 15:11  
fulfill 5:19  
full 4:17; 54:23; 78:3, 5;  
151:12, 25; 198:25  
full-well 174:9  
function 19:17; 22:25;  
33:10; 35:8; 44:7; 45:7, 24;  
82:21; 89:15; 118:9, 15,  
16; 128:4; 173:9; 187:6  
functional 22:15, 21, 22;  
123:13; 156:19; 172:25;  
176:17; 230:16  
functioning 20:6; 23:11,  
13; 24:4, 16, 23; 26:1, 9,  
16  
functions 45:15; 49:3;  
59:1  
fundamental 14:15; 15:2

Further 14:22; 53:21;  
54:16; 61:7; 85:4; 100:8;  
103:22; 123:12; 133:3;  
140:9; 155:3; 174:8;  
208:7; 236:7  
Furthermore 71:17  
future 64:20; 67:6;  
143:25; 154:14; 155:1;  
178:20; 196:17; 206:9, 12;  
208:13; 218:14

**G**

gain 90:13  
Gallo 115:25; 242:3  
GALLO-TORRES 6:8, 8;  
108:2; 116:5; 129:11;  
138:5  
game 171:5; 175:21  
games 170:16  
gamut 148:4; 178:3  
gangrenous 121:25;  
123:2  
gap 55:16  
gas 174:12  
gastric 160:22  
gastroenterologic  
193:19; 230:16  
gastroenterologist  
6:13; 19:11; 20:16, 21;  
194:3  
gastroenterologists  
167:4; 173:20; 191:12, 14,  
17, 18; 192:2, 5, 13, 16,  
19, 21, 22; 193:1, 13, 16,  
24; 194:2  
Gastroenterology 6:10;  
25:3; 49:12; 193:11, 22  
gastroesophageal  
25:13  
Gastrointestinal 58:25;  
100:16; 106:19; 108:3;  
116:2, 3; 123:13; 156:20  
gastronomia 94:17  
gather 34:4  
gathering 8:20; 231:19  
gastroenterologists  
192:14  
gave 78:24; 92:6; 99:5, 12  
geared 130:23  
gee 214:18; 235:18  
gender 21:13; 25:16;  
53:19  
general 8:5; 19:2; 23:12;  
25:6, 11; 26:11; 27:5; 51:1;  
52:9, 19; 53:14; 54:7; 55:2,  
16; 57:22; 58:24; 72:15;  
79:3, 7; 127:4; 131:13, 17;  
139:14; 172:10; 176:11;  
181:15; 188:11; 189:24;  
195:3, 4; 210:24  
generalized 187:8  
generally 135:2; 136:17;  
157:13  
generate 145:13

generated 135:3  
generic 23:7  
generous 167:9  
genetic 56:6  
gentlemen 19:10; 28:13;  
46:23; 106:18; 116:6;  
134:4  
genuine 110:5, 14  
geographical 69:1  
George 4:18; 6:12  
GERD 25:25; 26:3; 27:5  
geriatric 141:1  
Gershon 95:14, 15  
gets 127:14; 136:18;  
139:19; 141:8; 200:3;  
210:18; 235:1  
GI 6:5; 20:19; 21:22;  
42:22; 50:25; 71:17;  
94:25; 116:8; 149:9;  
164:19; 172:25; 173:19;  
176:17; 218:9, 17; 236:4  
given 29:7; 39:22; 78:3;  
94:15; 112:18; 134:14;  
148:6; 155:5; 158:25;  
164:23; 178:12; 181:6;  
187:18; 189:13; 194:21;  
199:22; 200:21; 215:7;  
219:21  
gives 101:1  
giving 83:24  
glad 43:12; 46:17; 184:14  
Glaxo 5:15; 8:15, 16;  
12:9, 18, 19, 25; 13:21;  
16:9, 21; 18:2, 15, 20;  
33:12, 18, 22; 34:1; 47:1;  
57:1; 58:25; 59:9; 60:16,  
19; 61:17; 62:12; 66:3, 10,  
11, 22; 67:5, 11; 71:24;  
75:13, 15; 76:12; 111:22;  
123:24; 126:3; 164:18;  
166:21; 167:2; 169:16;  
178:17, 23; 184:20;  
220:17; 224:22; 225:11;  
229:3; 230:6; 241:22  
Glaxo's 204:21  
global 32:8, 11, 16; 71:3;  
181:19  
glycocyanine 157:17  
goal 18:6; 54:3; 75:8;  
107:20; 178:8; 189:7, 10;  
204:9; 205:18, 19; 237:16;  
238:8  
goals 107:21, 22; 133:6;  
134:21; 149:19; 176:15;  
177:4, 6, 13; 194:16;  
201:24; 205:15; 207:14;  
236:7  
God 177:9  
goes 128:24; 201:22;  
226:8; 229:16  
Good 4:8; 8:12; 12:21;  
19:10; 28:13; 38:15, 25;  
41:15; 46:22; 89:13; 98:2;  
101:18; 104:4; 123:7;  
134:4; 142:21; 161:5;  
165:4; 169:10; 170:25;  
198:19, 20; 210:15;

214:17, 20; 222:5, 7;  
228:5; 236:14; 238:20;  
242:5  
goodly 81:23  
government 10:9; 11:1,  
16  
GPRD 55:3, 6  
grabbing 195:24  
graciously 164:10  
grade 40:13; 217:22  
Grainek 15:8; 18:12, 23,  
25; 19:6, 10; 30:16; 33:2;  
69:23; 76:17  
Grainek's 15:16  
grandchildren 168:5  
granted 4:18; 89:6  
graph 205:10  
graphical 111:20  
graphically 111:23  
graphics 61:16; 223:8  
graphs 32:1  
grappling 202:21  
great 20:4; 51:8; 92:21;  
95:7; 102:22; 104:5;  
214:8; 238:25; 239:22  
greater 44:9, 11, 15, 17,  
21, 24, 25; 60:12; 61:22;  
74:2; 84:17; 212:19  
green 5:20, 22  
grocery 169:25  
ground 197:10  
grounded 11:8  
group 21:10, 12; 22:2;  
24:8; 25:12, 15; 26:6, 12,  
13, 14, 19; 27:14; 76:21;  
81:8, 9; 82:7; 85:14;  
109:23, 23; 184:18; 200:  
203:7; 215:14; 223:22;  
230:17; 238:13  
groups 21:14; 24:5;  
25:17; 26:1; 53:14; 131:7  
144:25; 237:5  
guarantee 225:2  
guaranteed 229:8  
guess 85:12, 14, 25;  
93:1; 94:2; 95:3; 162:24;  
178:11; 190:9; 198:19;  
199:6; 200:4; 217:5;  
219:8; 222:15; 225:1;  
230:3; 239:25  
guessing 175:21  
guests 5:3; 58:22;  
106:17; 116:5; 133:4, 21  
163:5; 209:18  
guidance 73:10; 206:1  
232:15  
guide 49:7; 51:2; 56:20  
100:24; 105:25; 106:4;  
125:16, 19; 131:25;  
137:16, 17; 138:22, 23;  
140:3, 8; 141:6, 14, 16, 17;  
24; 142:3, 5; 155:8;  
207:18; 211:7; 222:10;  
223:3, 6, 13, 17, 21; 224  
10, 12, 23; 226:7, 13, 15  
20; 227:10, 16; 229:7, 1



183:23; 184:17  
identifying 62:5; 82:7;  
114:20; 179:3  
identity 124:14  
idiopathic 38:1; 200:16  
IFFGD 172:18; 174:14;  
176:18  
II 23:21; 29:2; 34:21; 35:1,  
5, 10, 12; 70:22; 82:19;  
89:19; 110:24  
III 6:7; 28:24; 29:11, 20;  
34:21; 35:1, 5, 10, 12, 15,  
18; 82:19; 109:19; 112:1;  
115:7, 12, 15; 144:4;  
145:3, 6; 146:2  
ileostomy 97:3, 4; 122:8;  
123:4  
ileus 34:19; 37:2  
ill 181:24  
illness 19:1, 5; 20:25;  
46:8; 101:11; 174:20;  
239:15  
illustrate 143:20  
illustrated 45:25; 73:12  
illustration 62:17; 65:21  
imagine 85:1; 220:16  
imaging 173:8  
imetrex 119:13  
imflximab 194:2  
immediate 124:13  
immediately 78:3;  
137:24  
imminent 132:21  
immunoallergic 187:1  
imodium 128:16, 21  
impact 15:7, 15; 18:25;  
25:4; 27:24; 70:4; 76:3;  
107:15, 19; 108:12;  
150:10; 152:24; 164:6;  
172:8; 175:2; 177:9, 10;  
206:19; 224:20; 230:13  
impacted 28:5  
impactful 15:1  
impaction 34:18; 38:5;  
74:5; 121:17, 18; 122:11,  
14  
impede 91:22, 23; 92:13,  
15  
implement 65:6; 67:18  
implementation 68:10,  
13; 131:1; 154:23; 177:15  
implemented 133:15  
implementing 65:4;  
149:15  
implicate 187:7  
imply 162:5  
importance 237:2  
important 5:23; 8:15;  
9:22; 35:8; 49:6, 25; 51:1;  
57:11; 59:17; 60:6, 22;  
62:23; 63:13; 64:4, 5, 13;  
66:15, 25; 68:12; 70:10;  
73:4; 82:17; 98:9; 102:7;  
104:23; 105:16, 20;  
117:23; 125:13, 21;

128:10; 130:22; 138:10;  
139:17; 140:4, 5, 18, 22;  
142:6, 14; 149:2; 154:21;  
174:17; 178:16; 185:3;  
187:13; 201:11; 202:4;  
207:1, 25; 211:19; 221:7;  
223:8, 9; 227:4, 7, 23;  
235:3; 237:21; 241:8, 14  
importantly 35:20;  
44:23; 107:9; 133:6  
impose 127:16  
imposed 126:11; 223:17  
imposing 230:11  
impossible 192:1  
impressed 98:10; 210:4  
impression 80:2  
improve 8:17; 10:6;  
111:11; 114:1, 6, 7;  
176:21; 190:22; 232:1, 9  
improved 32:16; 111:12;  
151:10, 17, 18, 19; 152:2;  
168:9  
improvement 13:7; 30:1,  
3, 8, 9, 18, 23; 31:4, 5;  
32:9, 11, 16, 18, 18; 33:4;  
46:9; 71:3; 111:14;  
113:11, 21; 114:10, 11;  
135:9; 239:6, 11  
improving 113:13, 14,  
16; 126:4  
imputed 93:18  
in-depth 57:8  
inability 79:14  
inadequate 93:3  
inadvertently 5:17  
inappropriate 62:6;  
69:14; 78:23; 92:19;  
110:16; 128:13  
inappropriately 39:23;  
203:24; 240:3  
incidence 51:6; 52:15,  
17, 18; 53:11; 55:3, 15;  
74:2, 19; 148:19, 19;  
194:20, 24; 195:3; 197:7  
include 17:8; 20:9; 51:17;  
52:11, 21; 58:9; 60:3;  
65:10, 14; 72:6; 74:7;  
89:10; 124:4, 21; 126:4;  
130:17; 131:4; 177:24;  
183:14; 205:24; 207:16;  
213:22; 222:1, 8; 231:16,  
20  
included 24:2; 40:23;  
45:4; 50:16; 62:9; 64:7, 13;  
75:15; 120:13; 124:6;  
127:6; 128:3; 140:3;  
150:6; 227:9; 231:21  
includes 47:7; 48:3, 13;  
53:4; 55:19; 56:17; 72:3;  
140:2, 7; 174:2  
including 34:18; 45:9;  
53:8; 56:6; 74:5; 80:25;  
103:10, 14; 105:2; 107:12;  
108:11; 124:16; 158:13;  
197:17; 207:17; 211:3  
inclusion 49:18; 144:12  
incoming 66:5

incomplete 19:20; 119:3;  
212:21  
incompleteness 93:19  
inconvenient 175:15  
incorporated 61:1;  
217:4  
incorrect 160:13;  
185:12; 186:11; 190:3  
incorrectly 191:20, 23;  
239:5  
increase 75:17; 197:6;  
212:16  
increased 27:20, 20;  
84:19, 19; 126:22; 147:21;  
175:2; 178:20; 179:6, 8,  
19; 180:1, 3; 188:13;  
192:20; 208:19; 233:4, 4  
increases 175:2  
Increasing 50:5  
incredible 78:22; 79:23  
increment 112:20  
incremental 70:19, 21  
increments 231:13  
incurred 21:11  
Indeed 75:4; 119:10;  
120:24; 147:11; 200:22;  
219:13; 240:3  
independent 30:12;  
135:1; 234:1, 8  
Indiana 45:11; 184:19  
indicate 14:17; 128:21  
indicated 83:3; 87:20;  
88:14; 107:3; 108:16;  
109:14, 15; 110:23; 111:1;  
144:21; 188:24; 189:8;  
202:7, 13; 212:7, 11;  
232:11; 237:4, 23; 239:15  
indicates 64:12; 136:23  
indicating 69:23  
indication 85:23; 108:18;  
109:14; 144:7; 149:11;  
152:21; 157:21, 22; 189:9,  
21; 191:4; 203:19; 208:12  
indications 9:17; 57:6;  
87:19; 126:5; 158:21;  
159:8; 189:14; 200:2;  
211:25; 212:7, 24; 213:8;  
214:12; 234:11; 238:14  
indirect 21:2; 22:3; 27:21  
indiscriminately 201:3  
individual 10:24; 22:16;  
23:13; 29:23; 36:11;  
37:10, 18, 21; 38:19; 46:8;  
62:2; 77:5; 81:19, 20;  
89:21; 93:13; 99:2; 109:6;  
148:5; 156:15; 174:4;  
195:20; 222:23  
individual's 22:21;  
23:11; 27:25  
individually 196:22  
individuals 20:17; 22:23;  
29:22; 30:20; 32:17;  
35:15; 39:20, 21; 45:6;  
46:1; 53:9; 55:8, 20; 78:14;  
82:9, 10, 11, 13, 20; 83:9,  
13, 15; 86:8, 10, 11, 18,

24; 89:16; 90:15, 18;  
93:16, 19  
induce 34:17  
induced 96:9  
industry 155:2; 228:13;  
235:8  
ineffective 99:8  
infants 141:1  
infectious 173:14  
inflammatory 41:21;  
51:18; 173:14  
inflow 233:5  
influenced 241:24  
Inform 125:5, 20; 155:6;  
205:16  
information 4:12, 20;  
13:17, 24; 14:1, 3; 17:4,  
21; 34:5, 6; 40:23; 43:2;  
49:2; 50:9; 51:25; 53:24;  
55:10; 59:17, 18, 20; 60:7,  
20; 61:1; 62:9, 23, 25;  
63:4, 13; 64:4, 5, 7, 12, 13,  
22; 65:2, 11, 18; 66:1, 11,  
15, 21, 25; 67:4, 4, 7, 21;  
69:11, 12, 21; 73:3, 5, 16,  
25; 75:23; 77:9; 78:13, 13,  
24; 79:6; 80:4, 12; 83:4;  
84:2; 85:7; 97:13; 104:18,  
23; 105:4, 17, 20; 124:18;  
125:13, 17; 127:12;  
128:11; 132:1; 134:10, 13,  
18, 19, 22, 24; 135:1, 9,  
10, 14, 17; 136:8, 10, 13,  
15; 137:4, 12; 140:6, 10,  
12, 18; 142:2, 7, 14, 14;  
155:4, 8, 12; 158:13, 15,  
22; 159:1; 160:10; 172:20;  
176:16; 177:18, 22;  
183:19; 184:15; 186:6;  
192:11; 193:7; 194:10;  
209:1; 211:20; 219:4;  
220:12, 15, 19; 221:1, 16;  
222:7, 13, 25; 223:10;  
225:3; 226:17; 228:7, 14,  
19; 233:10; 236:16  
informational 229:1  
informed 101:9, 11;  
102:1, 4  
infrequent 16:8; 50:15  
Ingleheim 5:9  
inhibition 91:8, 9  
inhibitor 153:2  
inhibitors 70:22  
Initial 54:21; 129:17;  
146:21; 166:17  
initially 186:15; 187:4;  
193:12, 22, 24; 194:13;  
197:20  
initiate 10:20; 12:18;  
82:12  
initiated 17:3; 41:4;  
57:17; 85:19, 20; 106:14;  
132:20; 213:16  
initiating 39:7; 55:14  
initiation 36:16; 42:13;  
43:21; 45:10; 117:21;  
121:13

initiative 16:21  
injuries 73:11  
injury 16:2; 126:24  
innovation 226:25  
innovative 98:20; 218:1;  
input 110:11; 115:23;  
215:1  
inquiring 42:21  
insert 9:3; 63:10, 18;  
64:5, 6; 91:16; 100:24;  
101:22, 25; 104:12, 12, 15;  
105:25; 106:3; 108:15;  
111:22, 22; 112:12;  
124:20, 22; 125:8, 9;  
126:7; 131:25; 155:7;  
159:9; 169:3, 4, 5; 225:6,  
13, 14, 15, 16, 17, 18;  
234:25  
inserts 65:9; 124:21;  
125:4, 18; 133:19; 135:19  
211:9  
inside 64:4, 6, 8; 105:4, 7  
insight 90:14  
install 63:16  
instance 83:8; 135:4;  
136:3; 137:18, 21; 138:15  
139:3, 22; 140:13; 213:21  
instances 188:25  
instead 79:19; 153:5  
Institute 7:14; 8:7; 10:11  
53:1; 107:17; 233:17  
Institutes 7:11  
instruction 229:7  
instructions 139:16;  
140:20, 22  
instrument 29:13; 32:11  
instruments 21:5  
integrated 47:23; 48:24  
49:9; 59:6; 76:5  
integration 105:11  
integrity 57:16  
intellect 8:21  
intend 13:20; 64:2; 65:2  
66:9, 24; 67:1, 18; 68:4  
intended 15:16; 62:22;  
63:2; 64:20; 68:4; 69:9, 1  
132:2; 134:13; 215:22, 2  
221:7  
intent 33:14; 62:1; 82:8;  
172:19  
inter-bowel 97:16  
inter-species 197:21  
interact 223:2  
interaction 72:13; 74:1  
23; 90:10; 91:10; 152:13  
173:3  
interactions 79:13, 16;  
90:5; 91:2  
intercourse 74:19  
interest 4:16, 24; 5:4, 1  
8:5; 11:20; 16:14; 49:8;  
56:14  
interested 16:22; 43:1  
110:10, 18; 114:20;  
115:23; 132:25; 150:18

interesting 28:10; 83:3; 147:19; 166:10; 186:15; 212:23  
ests 4:14  
face 240:14  
interior 37:5  
intermediary 102:14  
internal 49:3; 198:24  
international 31:16  
Internet 131:6; 220:10, 12, 13  
internist 6:19, 21; 8:5; 210:18, 24  
interpret 155:3  
interpreted 210:6  
interrupted 164:11  
interruption 35:17, 20, 21; 56:25; 78:9  
intertwined 190:21  
interval 32:22; 152:20  
intervals 68:15  
intervene 79:25  
intervention 10:18; 43:22, 25; 44:1; 107:18, 19; 108:11; 143:12, 13, 19, 20; 144:1; 149:22; 150:9; 152:9; 154:15; 155:18; 157:4; 200:6; 224:12; 228:25; 231:14; 233:20  
interventions 11:22; 16, 20; 132:25; 16, 18; 157:5; 177:7, 9; 197:4; 207:11; 229:1; 231:6; 232:16; 233:17; 234:2, 9  
intestinal 173:7; 213:13  
into 11:7; 20:25; 27:1; 29:1, 5; 36:19; 61:1; 81:5, 23; 88:8; 90:14; 106:8; 133:9; 134:7; 138:23; 142:22; 145:22; 146:23; 157:20; 165:10, 17; 166:5; 168:14; 185:5; 187:21; 202:3; 215:13; 217:3, 24; 222:7; 224:4; 225:11, 24; 228:4, 9  
intrigued 222:9  
introduce 6:1, 3; 18:11; 59:7; 61:25  
introduced 193:23, 25; 197:20  
introducing 63:1  
Introduction 4:2; 12:20; 52:21; 70:5; 75:13  
introductory 62:1; 63:1  
intuitive 183:9  
invasive 174:6  
stigated 179:22  
stigations 9:8  
investigators 23:20; 55:22; 66:10; 103:4; 152:5; 154:11; 172:24  
invite 12:17  
invited 5:3; 58:22  
involve 4:22

involved 11:2; 71:15; 222:11; 230:17  
involvement 5:1, 12  
involving 173:2; 197:17, 18  
IPA 153:12  
IRB 158:9  
irritable 8:18; 13:4; 15:12; 28:1; 29:15; 31:22; 35:9; 63:5; 64:22; 65:19; 69:24; 81:4, 5; 106:24; 108:16; 110:4, 6, 15; 123:12; 128:16; 132:14; 144:13; 149:10; 156:19; 157:23; 164:5, 6; 166:24; 167:17; 168:21, 23; 169:18; 206:16; 211:13; 212:12, 18; 219:23  
ischemia 37:15; 122:1; 123:3; 180:16, 16, 16, 21; 181:1; 182:12, 13; 233:2, 6, 11  
ischemic 16:7, 8; 33:10, 17, 19, 23; 34:2; 40:2, 5, 12, 18; 41:14; 42:19, 22, 25; 43:5, 7, 9, 14, 16, 17, 18; 45:23; 46:13; 48:8; 50:1, 23; 51:16; 52:10, 17; 53:10; 55:1, 15; 56:4; 57:14; 59:21; 61:14; 63:8; 66:18; 71:13, 18; 75:17; 77:12; 80:17; 86:20, 22; 87:13; 95:19; 98:4; 103:12; 104:1; 105:19; 116:13, 16, 20, 22; 117:2, 7, 10; 118:20; 119:1, 11, 14, 19, 22, 24; 120:1, 2, 4, 17, 18; 122:19; 123:16; 129:17, 19; 130:2, 5; 132:16; 146:3; 148:10, 11, 20; 149:2; 156:22; 162:19; 180:2, 6, 11, 12; 185:6; 188:19; 194:25; 195:1, 3, 16; 198:13, 21; 202:23, 24; 203:1; 206:17, 21; 213:14; 240:25  
Island 148:2  
isolating 175:12  
issue 4:9; 15:25; 16:18; 49:21; 73:7; 79:21; 82:17; 86:21; 89:3; 90:22; 100:4; 103:8; 109:2, 5, 10; 111:4, 9; 127:15; 139:20; 158:20; 159:5; 187:24; 188:6; 194:15; 195:21; 203:14; 207:25; 221:19; 227:17, 21; 231:11; 237:12  
issued 226:24  
issues 9:10; 10:21, 21; 11:8; 13:21; 14:15; 15:7; 49:20; 58:6; 72:16; 74:10; 78:20; 84:22; 103:7; 108:13, 22; 115:24; 144:23; 156:8, 11; 158:21; 184:20; 187:22; 209:16; 214:21  
item 65:17; 124:6  
items 62:11; 125:1, 4, 5; 143:10

iterative 10:19  
IV 95:9, 11

**J**

James 45:11; 76:18  
Janet 75:5  
January 150:1  
jaundice 45:4  
Jerry 7:16; 8:6  
Jim 184:19  
Joanne 8:2  
job 102:10; 189:14  
John 76:17  
Johns 8:1  
Journal 176:1  
journals 147:20; 193:19, 21, 22  
judge 82:14; 160:21  
judged 202:6  
judgment 88:17  
juggle 175:20  
July 43:3; 152:10; 205:7  
jumping 11:16  
Jun 41:25  
juncture 41:18  
June 34:6, 10, 11; 36:2; 40:8, 16; 117:4, 7; 129:21; 152:22, 25; 153:8, 17, 18; 154:8

**K**

Kay 76:18  
keep 12:14, 14; 38:19; 102:9; 191:5  
keeping 12:11  
Kent 12:17, 21, 24; 18:24; 33:8; 56:18; 60:19; 69:17, 20; 76:21; 79:3, 21; 80:8; 87:16; 91:25; 92:15; 98:25; 99:19, 22; 100:1; 101:20; 106:2; 193:9, 22; 194:9; 202:1, 3, 16, 22; 213:6; 221:21  
Kent's 104:11  
kept 168:3  
key 31:25; 47:3; 48:6, 20; 50:10; 60:10; 90:5, 20; 103:8; 217:5  
Keystone 227:13  
kill 172:11, 17  
killer 172:15  
kind 136:13; 155:8; 168:23; 182:4; 188:12; 191:1; 197:6; 201:15; 208:16; 210:14; 220:5, 6; 221:14; 229:18; 234:16; 237:8  
kit 63:22  
kits 64:18; 67:7  
knew 169:1  
knowing 105:3; 174:9;

203:10; 210:16  
knowledge 55:17; 67:4; 68:6, 23; 104:25; 191:8; 194:7  
known 9:14; 11:11; 78:19; 79:1; 94:13; 115:10; 127:5; 135:22; 144:25; 145:21; 213:15; 228:13; 229:8  
knows 81:19, 20; 83:21; 158:16  
KRAMER 7:10, 10; 89:2; 91:14, 15; 92:12; 100:17; 104:19, 20; 182:15, 16; 189:22, 23; 190:7; 203:21; 208:20, 21; 231:4  
Krause 164:12, 16, 16; 165:21; 166:7, 15, 18

**L**

label 10:2; 45:3; 79:20; 124:12; 141:14; 151:22; 154:9; 159:23; 160:8; 211:24; 221:21  
labeled 9:14; 31:11; 75:10; 85:23; 147:16  
labeling 9:2, 15, 17, 19, 21; 11:3; 14:1, 2, 8; 16:3, 4; 17:22; 18:1, 3, 4; 61:3; 72:4, 14; 73:2, 17; 74:12, 22; 75:12, 14, 21; 79:17; 82:2, 9; 87:17; 107:12; 108:12, 12, 18; 124:4, 12, 21; 125:10, 11; 126:1, 2; 135:16, 19, 23, 24, 24; 136:4, 9, 13, 14, 20; 137:3, 6, 9, 11, 19, 21; 139:6, 8; 141:24; 142:5; 143:9, 21; 149:16; 150:10, 17, 18; 152:1, 2, 25; 154:8, 16, 17, 18; 155:16, 23; 157:3; 161:19; 204:13; 207:17, 25; 208:18; 209:16; 210:6, 15, 22; 231:23; 233:19; 234:9  
laboratory 118:8  
lack 15:12; 111:2; 129:24; 130:1  
ladies 19:9; 28:13; 46:23; 106:18; 116:6; 134:4  
lady 200:20; 201:2; 222:12  
lags 54:11  
LAINE 6:10, 10; 15:21; 80:12; 81:22; 83:23; 84:9; 85:1, 9, 25; 86:4, 20; 87:13, 16; 88:20; 158:18, 19; 159:22; 161:9; 178:2; 183:7, 8; 192:17, 18; 195:11; 196:14; 199:6; 203:7; 205:22; 212:9, 23; 213:8, 20; 214:3; 215:18; 216:3; 219:2  
Laine's 94:4; 184:2  
lamina 120:22  
language 98:16; 100:14;

125:14; 138:25; 139:1, 7; 222:20, 22  
languages 217:24  
laparotomy 42:5  
large 11:7; 31:16; 36:21; 42:20, 22; 46:7; 50:10; 51:11; 52:5; 55:20; 70:3; 71:17; 78:13; 84:21; 87:11; 90:13, 24; 120:15; 150:11; 227:22  
large-scale 134:20  
largely 112:9  
larger 80:22  
largest 53:2  
Larry 180:5; 181:21  
last 39:4; 43:19; 72:13; 84:1, 1, 1, 4, 90:22; 105:22; 112:8; 128:18; 143:14; 144:15; 150:17; 158:22; 164:19, 20, 23; 166:17; 167:4; 176:13; 183:15; 199:20; 213:1; 223:4; 232:3; 235:12, 17  
Lastly 26:19; 27:22; 59:19; 62:11; 67:6; 69:14  
late 198:2  
lately 171:5  
later 38:10, 15, 16; 39:1; 41:16, 22; 88:25; 120:19; 147:15; 150:1; 156:4; 185:8; 187:10; 189:9; 194:14; 198:1; 207:7; 237:15  
latest 97:12  
laudable 211:19  
Laughter 7:3; 157:9; 160:23; 167:24; 185:17; 198:7; 205:20; 221:22; 236:20  
launched 49:8; 150:1; 193:10, 10  
lavatory 168:8  
law 5:19; 141:6; 224:14, 15  
Lawrence 43:9; 76:16  
lawyers 102:13  
laxative 35:10, 11; 56:24; 78:9  
laxatives 82:15; 222:5  
lay 125:13  
lead 27:19, 20; 98:23; 126:24; 180:1  
Leader 6:9  
leaders 98:19, 22  
leading 233:6  
leads 202:3  
leaflet 125:17  
lean 208:21  
leaning 229:13  
learn 11:25; 167:6; 236:13, 14  
learned 79:12; 208:22, 23  
least 43:8, 19; 81:23; 87:23; 93:16; 96:18;









psychosocial 231:8  
public 5:4, 18; 8:13, 15, 21; 10:4, 12, 19, 20; 12:12; 19:4; 131:5; 134:5; 137:8; 140:7; 142:12; 147:22; 164:15; 176:11; 209:9; 223:14  
publish 147:19  
published 21:8; 23:6; 25:3  
publishing 211:9  
pull 225:16; 226:1  
pulled 99:14  
pulmonary 22:24, 24  
purchase 135:3  
pure 80:15  
purpose 87:11; 133:22; 189:13; 197:8  
purposes 197:15; 240:22  
purse 168:3  
pursue 182:25  
pursued 209:5  
purview 228:20  
push 194:15; 220:21; 234:21; 236:7; 237:5, 10; 239:17  
put 82:23; 83:16; 89:17; 92:21; 94:5, 8; 119:9; 127:21, 22; 142:14, 22; 155:8; 157:7; 165:12; 166:5; 170:7; 202:9; 213:6; 226:5; 228:17  
putting 89:9; 211:9

**Q**

QT 145:24; 152:20; 153:2  
quality 126:15; 167:21  
Quality 15:9; 21:5; 22:13, 18; 23:1, 2, 8, 10, 18; 24:6, 23; 25:5; 27:25; 28:7; 46:17; 70:1; 135:9; 174:25  
quantify 47:25  
quantitative 68:23; 219:8  
quantities 63:9; 64:8  
Quarterly 49:2; 54:18  
quick 87:16; 142:10  
quickly 143:16; 186:4  
quite 8:20; 91:9; 175:7; 185:5; 208:22  
quoting 75:4

**R**

race 21:13  
Race/ethnicity 144:23  
races 144:24  
Raczkowski 106:14, 17; 123:22; 133:20; 138:5; 143:5; 148:14; 156:7; 157:7, 12, 19; 161:25; 162:1, 8; 198:10, 12;

214:21; 215:20  
radiographic 19:22  
raise 176:16  
raised 89:4; 100:5; 162:17  
raises 74:10; 187:7  
raising 172:19  
ran 81:23  
randomized 56:22; 112:14  
range 23:8; 147:25; 155:24; 175:14  
ranges 20:1; 51:19  
ranging 19:18; 113:22  
rapidly 30:5; 134:7  
rare 16:14; 39:18; 46:14; 50:15; 71:20; 72:17; 145:2, 13; 202:25  
rash 41:19  
rat 96:1, 1  
rate 21:16; 40:7, 11; 84:17; 160:24; 201:18, 21; 202:16; 203:3; 226:4; 233:8  
rates 22:6; 42:21; 45:17; 53:12; 54:25; 70:14; 127:6; 162:3; 193:5; 194:17; 236:5; 237:13  
rather 19:2; 33:25; 113:14; 133:24; 165:25; 172:17; 173:12; 182:5; 223:10  
ratio 46:15; 115:20, 22  
rational 28:20; 191:5  
rationale 139:18  
re-anastomosis 97:14  
re-labelings 150:5; 154:20  
re-prepped 36:23  
re-review 95:23  
reach 69:10  
reached 52:8; 72:15; 238:22  
reaction 127:17; 146:10; 148:5  
reactions 126:10, 11, 13; 127:5; 128:1; 131:18; 148:3  
read 9:20; 88:20; 94:23; 97:6; 140:9; 169:3, 4, 5, 10; 213:4; 214:18, 20; 218:5, 22, 23, 24; 221:4  
readmitted 38:18, 21  
reaffirm 233:16, 22  
real 10:3; 50:11; 76:1; 167:21; 191:22; 198:22; 201:23; 218:10, 25; 237:12  
real-world 86:4; 88:23  
reality 12:4  
realize 9:25; 204:20  
realized 133:7  
realizing 9:21  
really 79:1; 80:4, 6, 14,

18, 19; 82:25; 83:10; 88:25; 89:9, 10; 90:6; 91:9; 97:20; 98:9, 11, 14, 19, 22; 100:21, 23; 101:18; 140:4; 147:13, 21; 148:4, 5, 16; 154:5, 7, 18, 21; 156:3; 166:18; 170:12, 25; 178:18; 181:7; 182:20; 183:22; 188:21; 196:4; 197:15; 198:3; 199:6; 200:19; 204:7; 208:11; 209:1, 17; 210:16; 211:10, 22; 214:18; 216:25; 217:14, 18, 22, 22, 24; 218:2, 2, 15; 219:9, 12; 220:10, 14; 222:9; 223:8; 229:15, 19; 230:22; 237:3, 4, 6, 9, 10; 238:4, 6, 24; 240:12  
reams 162:20  
reason 65:2; 78:1, 11; 79:8; 134:8; 146:17; 209:7; 227:15; 238:24  
reasonable 126:16; 178:3; 186:19; 192:20; 195:22; 206:9  
reasonably 54:8; 141:2  
reasoning 160:20  
reasons 139:16; 189:13; 197:2; 208:2  
reassess 204:14; 205:1; 236:4, 23  
reassurance 197:10  
reassured 197:12  
reassuring 130:4  
recall 15:22; 82:19  
receive 60:7; 64:20, 22; 95:24; 145:11, 14; 174:4, 6; 176:3  
received 13:5; 14:12; 16:6, 8; 17:16, 21; 38:6; 19; 84:24; 107:1; 129:7; 144:22; 150:2; 151:15; 152:12; 168:13; 170:19; 191:23; 225:8  
receives 132:1  
receiving 5:8; 52:7, 16, 20; 56:12; 63:11; 110:15; 117:25; 201:14; 234:14  
Recent 10:10; 18:4; 73:12; 135:8; 173:15; 175:25; 183:11, 14; 213:3, 20  
recently 9:16; 20:12; 32:5; 49:8; 71:2, 17; 74:14; 78:21; 94:9; 135:7; 171:2, 6; 172:24; 183:21; 191:16; 208:13; 214:4  
receptor 28:17; 96:17  
receptors 28:18; 94:24; 95:15, 17; 96:19  
recess 106:12  
recessed 163:11  
rechallenge 146:11  
recognition 63:7; 66:17  
recognitions 61:14  
recognizable 50:1

recognize 59:21; 76:10; 125:6; 147:8; 209:10; 227:2, 23; 229:17  
recognized 34:17; 43:8; 73:22; 74:2, 21; 175:24  
recognizes 143:9  
recognizing 137:22  
recommend 150:19; 189:8; 221:12; 236:1, 1, 3  
recommendation 13:9; 187:25; 191:25; 194:13; 230:9  
recommendations 96:24; 106:10; 150:7; 155:13; 234:10  
recommended 9:2; 59:22; 61:15; 63:8; 66:18; 150:16; 151:22, 25; 154:23; 204:23; 205:3  
recommending 230:4; 234:17  
reconcile 82:22  
reconciled 33:18  
reconvene 236:3  
record 4:10; 5:2, 6; 103:4; 149:8; 156:1  
records 51:14; 55:7, 18; 103:22  
recovered 37:11  
recruiting 84:22  
rectal 119:18, 20; 120:10  
rectum 98:1  
recurrent 20:5; 87:24; 212:14  
recurring 146:13  
redesign 65:8; 236:15  
reduce 207:13  
reducing 50:4  
reduction 30:21; 56:25; 78:9, 16; 154:7; 241:10  
redundancy 12:15  
reemphasize 220:9; 221:25  
reinforce 61:11; 63:5; 23; 64:15, 21; 67:7, 24; 100:11; 105:9; 134:13; 220:6  
reinforced 61:8  
Reevaluation 106:16, 20; 107:2; 108:1  
refer 117:8, 14, 17; 126:23; 136:13  
Reference 9:5; 104:11; 105:6; 140:17  
referrals 89:6  
referred 60:13; 67:17; 70:5; 118:22; 162:11; 210:24  
referring 118:2, 3  
refilled 166:16  
refills 77:1, 5; 166:14, 15  
refine 53:7  
refining 56:2  
reflect 17:11; 81:16, 17;

155:24  
reflected 75:4  
reflection 14:9  
reflects 220:23  
reflux 25:13  
reformation 203:22  
refugees 174:15  
regard 4:9; 15:19; 16:4; 87:17; 146:6; 154:9  
regarding 13:17; 15:24; 16:23; 72:14; 73:4; 74:11; 76:15; 77:16; 78:19; 109:2; 133:24; 143:25; 145:1; 150:10; 152:9; 182:15; 184:20; 207:6, 12; 208:5; 217:8; 219:15; 233:14  
regardless 211:4  
region 43:25; 44:2  
register 65:15  
registries 187:18  
regulate 189:14; 190:25  
regulated 4:14; 241:5  
regulation 106:1; 137:5; 139:23; 140:2; 141:13, 18; 223:13, 24, 25; 224:14; 225:2, 7; 227:23; 231:20  
regulations 135:20, 21; 138:23; 141:22; 231:22  
regulatory 226:11  
reign 242:4  
reiterate 183:9; 241:8  
relate 57:13  
related 13:22; 16:14; 23:1; 25:5; 28:7; 36:1; 37:17; 58:7; 74:18, 24; 75:1; 85:15; 86:20; 104:20; 108:3; 113:11; 158:21; 177:2; 185:15; 188:1; 201:8; 222:6  
relating 83:4; 103:7; 104:7  
relationship 126:17; 129:4, 18, 25; 130:9; 145:19; 169:11; 170:3; 174:1; 188:7; 199:22, 23  
relative 16:12; 80:15; 138:1; 233:2, 6, 11  
relatively 14:23; 70:6; 125:19; 162:7; 183:15; 184:13; 203:2  
relaxed 166:8  
releasable 5:19  
release 185:2  
released 207:3  
releases 130:18  
relegated 152:21  
relevant 35:9; 62:8; 160:6; 184:21  
relief 8:18; 29:12, 13, 15, 22; 31:24, 24; 32:1; 70:18; 93:14, 17, 18; 112:5, 7; 161:12; 162:12  
remain 136:1  
remainder 30:3















236:2, 3, 21; 237:18;  
238:22; 239:5; 241:15  
**years** 21:7; 23:6; 54:23;  
95:16, 25; 117:19,  
128:18; 136:3;  
17:17; 158:3; 164:19, 20,  
21; 166:25; 167:4, 4;  
169:19, 19; 175:14;  
178:23; 191:19; 216:18;  
220:14; 224:6; 227:12  
**yellow** 30:2; 104:23  
**yesterday** 5:25; 19:3, 4;  
40:21; 81:2, 7; 84:10;  
159:16; 164:6; 205:2  
**yesterday's** 159:7  
**yielding** 40:7, 10  
**York** 6:21, 23; 101:6, 16;  
143:15  
**young** 188:19; 222:12  
**younger** 181:9, 18;  
186:16; 188:20

**Z**

**Zantac** 160:21, 25  
**zero** 203:7