This is **Exhibit B** referred to in the Affidavit of **Stephen Walter** sworn before me this day of May, 2007.

A Commissioner, etc.

consult their physician or their belief that they needed a diagnostic test or a medicine, or as an information source they used (adjusted odds ratio [OR] 2.6, 95% confidence interval [CI] 1.5-4.3). More patients in Sacramento also said that they had conditions that could be treated by an advertised drug (29.4% v. 21.9%: adjusted OR 1.4, 95% CI 1.1-1.8). Patients particularly identified their allergies as conditions that could be treated by an advertised drug: 88 (12.9%) in Sacramento compared with 42 (5.6%) in Vancouver.

Prescription drug requests

Sacramento patients were twice as likely to request medicines as patients in Vancouver and over twice as likely to request advertised crugs (Table 3). After eliminating 12 consultations in which requested drugs were prescription-only drugs in 1 country and OTC drugs in the other, request rates remained substantially different: 14.2% in Sacramento versus 8.8% in Vancouver (p < 0.01) (data not shown).

Advertising exposure was measured through the number of listed products a person had seen advertised, identification with an advertised condition and use of advertising as an information source. In Sacramento, all 3 measures were associated with a higher probability of DTCA drug requests. In Vancouver, only the use of advertising as an information source (3.5% of patients) was significantly associated with DTCA drug requests (Table 3). Fig. 2 compares the number of listed drugs patients had seen advertised with their request rates (x2 for linear trend = 18.5, p < 0.001).

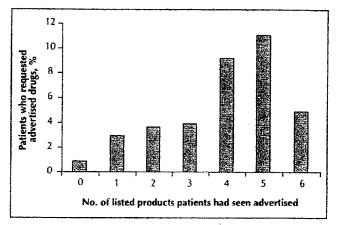


Fig. 2: Proportion of patients who requested DTCA drugs by the number of listed products they remembered having seen advertised. Loratadine (Claritin) was omitted from this analysis. because it had over-the-counter status in Canada. DTCA = direct-to-consumer advertising.

	No. (and %) of patients			
Advertisements seen in previous year	Sacramento n = 683	Vancouver n = 748	OR (95% CI)†	Adjusted OR (95% CI)‡
No. of products*			· · · · · · · · · · · · · · · · · · ·	
0	13 (1.9)	72 (9.6)	0.2 (0.1-0.4)	0.2 (0.1-0.4)
1-5	171 (25.0)	295 (39.4)	0.5 (0.4-0.6)	0.5 (0.4-0.6)
≥ 6	469 (68.7)	359 (48.0)	2.5 (1.9-3.2)	2.7 (2.1–3.6)
Specific product advertisements			,	
Viagra (sildenafil citrate)	611 (89.5)	592 (79.1)	2.2 (1.6-3.2)	2.0 (1.4-2.9)
Prozac (fluoxetine hydrochloride)	487 (71.3)	426 (57.0)	1.9 (1.5-2.3)	1.8 (1.4–2.3)
Zyban (bupropion hydrochloride)	487 (71.3)	334 (44.7)	3.1 (2.4-3.9)	3.5 (2.7-4.7)
Propecia (finasteride)	357 (52.3)	105 (14.0)	6.7 (5.1–8.8)	7.0 (5.1–9.6)
Depo-Provera		,		, , , , , , , , , , , , , , , , , , , ,
(medroxyprogesterone acetate)	210 (30.7)	118 (15.8)	2.3 (1.7-3.2)	2.6 (1.8-3.6)
Evista (raloxifene hydrochloride)	83 (12.2)	27 (3.6)	3.7 (2.3-5.8)	4.6 (2.8-7.5)
Claritin (loratadine)	586 (85.8)	625 (83.6)	1.2 (0.9-1.6)	1.2 (0.8-1.7)
Patients who had seen advertisements for > 3 of 6 listed		•	·	, ,
products§	321 (47.0)	118 (15.8)	4.7 (3.6-6.2)	5.9 (4.5-7.7)
Patients who identified themselves as having a condition treatable by	227 (22 1)			
an advertised drug	201 (29.4)	164 (21.9)	1.5 (1.2–1.9)	1.4 (1.1–1.8)
Patients who reported using advertising as an information				
source	56 (8.2)	26 (3.5)	2.5 (1.5-4.3)	2.6 (1.5-4.3)

Note: OR = odds ratio, CI = confidence interval

^{*}Percentages do not add up to 100%; 4.4% of values are missing for the Sacramento sample and 3% for the Vancouver sample.

[†]Odds ratios based on a general estimation equation (GEF) analysis.

Adjusted orids ratios based on a GEE analysis controlling for age, sex, health status, income, education and drug payment

[§]Excludes Claritin tover-the-counter status in Canada)

We tested the robustness of city of residence as an independent factor that might influence request rates by including it in the same model as these 3 measures of individual advertising exposure. The coefficient for city of residence became smaller and marginally nonsignificant when adjusted for advertising exposure (OR 1.5, 95% CI 0.9–2.6; p = 0.06); advertising exposure remained highly significant (Table 4).

Patients requested 37 different DTCA drugs, 7 of which were requested by ≥ 3 patients. One-quarter of Vancouver DTCA drug requests were for products advertised in Canada. The most commonly requested nonadvertised drugs were antibiotics, anxiolytic or hypnotic drugs, and cardiovascular drugs.

Prescribing

More patients in Sacramento than in Vancouver received 1 or more new prescriptions: 41.3% versus 24.9% (adjusted OR 2.1, 95% CI 1.6–2.8; p < 0.01) (Table 5). The prescribing rate was higher overall in Sacramento, but

more Vancouver patients received 1 or more refills: 25% versus 18% (data not shown).

Physicians fulfilled most requests for prescriptions in both settings. In Sacramento 80% of patients who requested prescriptions received them, as compared with 63% in Vancouver (Table 5). The main difference was in the prescribing rate for requested nonadvertised drugs (81.4% v. 57.1%), although this difference was no longer statistically significant after adjusting for patient and physician characteristics (adjusted OR 2.2, 95% CI 0.8-6.2). Prescribing rates for advertised drugs differed less (77.6% v. 72.0%: adjusted OR 2.1, 95% CI 0.5-9.6).

Patients who requested medicines were very likely to receive 1 or more new prescriptions, either for the drugs they requested or alternatives. Indeed, for patients requesting DTCA drugs, the odds of receiving a prescription (for any drug) were 16.9 times those of patients who did not request a medicine (adjusted OR 16.9, 95% CI 7.5–38.2) (Table 5).

In order to judge physician confidence in treatment choice for each new prescription, we asked, "If you were treating another similar patient with the same condition,

Table 3: Patients' requests for		0		
prescriptions	No. (and %) of patients		OR (95% CI)*	Adjusted OR (95% CI)†
Prescriptions requested	Sacramento	Vancouver	Sacramento v	. Vancouver
≥ 1 new prescriptions requested (any drug) ≥ 1 DTCA drugs requested	108/683 (15.8) 49/683 (7.2)	67/748 (9.0) 25/748 (3.3)	1.9 (1.3–2.8) 2.2 (1.3–3.8)	2.0 (1.3-3.1) 2.2 (1.2-4.1)
Had the patient seen advertisements for > 3 of 6 listed drugs?‡	Yes	No	Higher v. lower	
≥ 1 DTCA drugs requested, Sacramento ≥ 1 DTCA drugs requested,	34/321 (10.6)	15/362 (4.1)	2.7 (1.6–4.7)	2.8 (1.6-4.9)
Vancouver	7/118 (5.9)	18/630 (2.9)	2.1 (0.8-5.9)	1.8 (0.6-5.1)
Did the patient identify himself or herself as having a condition (reatable by an advertised drug?‡	Yes	No	Condition v. r.	no candition
2.1 DTCA drugs requested, facramento 2.1 DTCA drugs requested, (ancouver	30/201 (14.9)	19/482 (3.9)	4.2 (2.5–7.3)	4.6 (2.5–8.5)
Oid the patient report using advertising as an information ource!‡	8/164 (4.9) Yes	17/584 (2.9) No	1.7 (0.8–3.5) Advertising use	1.9 (0.9-3.9)
: 1 DTCA drugs requested, acramento : 1 DTCA drugs requested,	10/56 (17.9)	39/627 (6.2)	3.3 (1.8-6.1)	3.9 (2.2-7.0)
/ancouver	3/26 (11.5)	22/722 (3.0)	4.0 (1.2-13.4)	4.1 (1.3-13.6)

Note: DTCA = direct-to-consumer advertising

^{*}Odds ratios based on a GEE analysis

[†]Adjusted adds ratios based on a GEE analysis controlling for age, sex, health status, income, education and drug payment

[#]Denominators derived from data in Table 2.

would you prescribe this drug?" We judged an answer of "very likely" to indicate confidence in treatment choice, whereas "possibly" or "unlikely" would indicate some degree of ambivalence. In both settings, physicians were more

likely to express ambivalence about drugs patients had requested, particularly advertised drugs, than nonrequested drugs (adjusted OR for requested DTCA drugs 7.1 in Sacramento [95% CI 2.5-19.8], 14.5 in Vancouver [95%

Table 4: DTCA drug requests as a function of location and individual advertising exposure*

Factors associated with drug requests	No. (and %) of patients who requested DTCA drugs $n = 74$	Adjusted OR (95% CI)
Patient lives in Sacramento	49 (66.2)	1.5 (0.9-2.6)
Has seen advertisements for > 3 listed drugs	41 (55.4)	2.1 (1.3-3.3)
Has a condition treated by an advertised drug	38 (51.4)	2.7 (1.8-4.2)
Uses advertising as an information source	13 (17.6)	2.9 (1.7-5.1)

^{*}GEE model with city of residence and 3 advertising exposure variables entered, as well as potential confounders (age, sex, health status, income, education, drug payment, physician's sex and graduation year); backward stepwise regression analysis with removal of potential confounders if p > 0.1.

Table 5: Prescribing rates during surveyed consultations

	No. (and %) of patients			
Prescriptions requested and received	Sacramento	Vancouver	– OR (95% CI)*	Adjusted OR (95% CI)†
Patient received ≥ 1 prescriptions (new and refill prescriptions)	300/(02/57.1)			
•	390/683 (57.1)	350/748 (46.8)	1.5 (1.1–2.0)	1.4 (1.0–2.0)
Patient received ≥ 1 new prescriptions	282/683 (41,3)	186/748 (24.9)	2.1 (1.6-2.7)	2.1 (1.6-2.8)
Patient requested ≥ 1 new prescriptions and received the requested prescription(s) (any drug requested)	86/683 (12.6)	42/748 (5.6)	2.4 (1.5-3.7)	2.5 (1.6–3.9)
Patients described above as a proportion of patients who requested any drugs‡	86/108 (79.6)	42/67 (62.6)	2.0 (0.9-4.6)	2.1 (0.9-5.3)
Patient requested ≥ 1 new prescriptions for DTCA drug and received the requested prescription	38/683 (5.6)	18/748 (2.4)	2.4 (1.3–4.3)	2.3 (1.3-4.3)
Patients described above as a proportion of patients who requested DTCA drugs‡	38/49 (77.6)	18/25 (72.0)	1.4 (0.4–4.8)	2.1 (0.5–9.6)
Patient requested ≥ 1 new prescriptions for a non-DTCA drug and received the requested prescription	48/683 (7.0)	24/748 (3.2)	2.2 (1.3-3.9)	2.0 (1.1–3.7)
Patients described above as a proportion of batients who requested non-DTCA drugs‡	48/59 (81.4)	24/42 (57.1)	3.0 (1.2-7.8)	2.2 (0.8-6.2)
Patient requested DTCA drugs and received 1 new prescriptions (any prescription) as 1 proportion of patients who requested DTCA drugs‡	42/49 (85.7)	22/25 (88.0)	0.9 (0.2-4.1)	0.8 (0.1–5.7)
Patient requested no.n-DTCA drugs and eccived ≥ 1 new prescriptions (any prescription)	47/59 (79.7)	. No continues the second resistance and the	1.6 (0.6–4.5)	1.2 (0.4–3.4)
Probability of receiving ≥ 1 new prescriptions a	mong drug requesters	v. nonrequesters (combin	ned Sacramento and Val	ncouver samples)
Prescription	Drug request	No drug request		
DTCA drug	64/74 (86.5)	329/1256 (26.2)	17.5 (8.1–37.7)	16.9 (7.5–38.2)
von-DTCA drug	75/101 (74.3)	329/1256 (26.2)	7.8 (4.8–12.9)	7.9 (4.8–13.2)

#Denominators derived from data in Table 3.

^{*}Odds ratios based on a general estimation equation (GEE) analysis.
†Adjusted odds ratios based on a GEE analysis controlling for age, sex, health status, income, education, drug payment, doctor's sex and graduation year.

CI 2.6-81.4]) (Table 6). Physicians were also more likely to judge patients to be knowledgeable about a drug if they had requested it.

Interpretation

We found that Sacramento patients reported more advertising exposure and requested more advertised drugs than patients in Vancouver and, in both settings, patients with higher exposure to advertising requested more advertised drugs. The prescribing rate for requested advertised drugs was similar, being about 75%.

Physicians judged 50% of prescriptions for requested DTCA drugs to be a "possible" or "unlikely" choice for similar patients. A key argument made in favour of DTCA is that patients are protected because, ultimately, the physician decides whether or not to prescribe." We could not evaluate treatment appropriateness, but if physicians prescribe products that they would not have chosen otherwise, the protection offered by prescription-only status is questionable. In some cases, patients may be right and physicians wrong; however, patients do not obtain sufficient information from advertising to accurately self-diagnose or to choose the best available treatment.17 If physicians are less familiar with a product, they may also be less aware of contraindications, interactions and adverse effects.

DTCA appears to affect prescribing volume as well as product choice. Fatients who requested DTCA drugs were nearly 17 times as likely to receive 1 or more new prescriptions as patients who did not request medicines. Nearly 9 of 10 such patients received prescriptions, either for the

drug they had requested or an alternative.

Patients' requests for advertised medicines could lead to important health benefits if patients seek and obtain appropriate care, perhaps at an earlier stage, and thus avoid disease complications and admissions to hospital. However, many requested advertised products were "lifestyle drugs"18 or symptomatic treatments. Such therapies may relieve distress or discomfort but are unlikely to prevent admission to hospital or serious morbidity. With a trend toward treatment of milder conditions, a shift may also occur in the balance between expected benefit and potential harm.

We linked self-reported patient exposure to DTCA to patient requests for medicines and prescriptions within surveyed primary care consultations. Other consumer surveys on DTCA have relied on recall of past behaviours over long or indeterminate time periods, introducing a potential for recall bias. We also compared otherwise similar consultations and prescribing decisions that were or were not directly affected by DTCA. This internal comparison group allowed for an examination of the direction of effect of DTCA on prescribing volume and on physicians' confidence in treatment choice. In contrast, the claim made by Weissman and colleagues that DTCA leads to important new diagnoses" has been criticized because their survey lacked a control group, making it impossible to know whether DTCA leads to fewer or more such diagnoses than occur in other patient visits.20 A physician survey carried out by the US Food and Drug Administration on consultations influenced by DTCA has been subject to similar critique."

This was a cross-sectional survey based on cluster sam-

Table 6: New prescriptions: physicians' opinions of treatment choice and patient knowledge*

	No. (and 9	6) of prescriptions		Adjusted OR (95% CI)§
Patients	Prescribed drug was not requested by the patient	Prescribed drug was requested by the patient †	OR (95% CI)‡	
Physician judged	I the medicine to be a "possible	" or "unlikely" choice (v. a very li	kely choice) for similar j	patients
Sacramento	39/322 (12.1)	Any drug 45/98 (45.9) ¶	5.0 (2.6-9.5)	5.4 (2.7-11.0)
		DTCA drug 20/42 (47.6)	5.7 (2.3-14.3)	7.1 (2.5-19.8)
Vancouver	23/178 (12.9)	Any drug 17/45 (37.8)	4.1 (1.8-9.0)	6.3 (1.8-22.3)
		DTCA drug 10/18 (55.6)	8.3 (2.7-25.1)	14.5 (2.6-81.4)
Total	62/500 (12.4)	Any drug 62/143 (43.4)	4.7 (2.8-7.7)	5.3 (3.1-9.2)
		DTCA drug 30/60 (50.0)	6.4 (3.1-13.0)	8.4 (3.8-14.7)
Physician judged	the patient to be knowledgeab.	le about the medicine		
Sacramento	81/322 (25.2)	Any drug 70/98 (71.4)	8.5 (4.5–15.9)	9.4 (4.8-18.6)
		DTCA drug 28/42 (66.6)	6.5 (3.1-13.5)	8.0 (3.7-13.0)
Vancouver	37/178 (20.8)	Any drug 24/45 (53.3)	3.8 (1.8-8.1)	4.0 (1.9-8.6)
	-	DTCA drug 11/18 (61.1)	6.0 (2.1–17.0)	6.3 (2.1-18.9)
Total	118/500 (23.6)	Any drug 94/143 (65.7)	6.3 (3.9-10.4)	6.5 (3.9-10.8)
		DTCA drug 39/60 (65.0)	6.3 (3.4-11.5)	6.9 (3.7-13.0)

^{*}The unit of analysis is each single newly initiated prescription (n = 643; 420 in Sacramento and 223 in Vancouver), not each patient, because physicians recorded their opinion separately for each newly prescribed drug. Some patients requested more than 1 medicines in total, 143 were requested, 60 of which were DTCA drugs The prescription was for the specific brand the patient requested. †Unadjusted GEE analysis.

SAdjusted ORs bised on a GFF analysis controlling for age, sex, health status, income, education, drug payment, and physician's sex and graduation year.
The "any drug" denominator includes both DTCA and non-DTCA drugs.

pling, and the results are therefore exploratory. Participating physicians may not be broadly representative because of a possible volunteer bias and their links to medical faculties, and the patient population was relatively affluent. In addition, whereas most Sacramento physicians were salaried, Vancouver physicians mainly worked on a fee-for-service basis. This difference is unlikely to explain the higher prescribing rates in Sacramento, because incentives to prescribe are greater under a fee-for-service system.12 The Sacramento survey took place 10 months later than the Vancouver survey, which may have marginally exaggerated observed exposure differences. However, the relation between individual exposure and requests for medicines would not have been affected.

In a comparison of 2 countries, there is a risk of "confounding by culture," that is, mistakenly attributing cultural differences in behaviour to differences in the advertising environment. However, this cannot account for the finding in both settings that individuals who reported greater advertising exposure had higher request rates for advertised drugs. The most plausible explanation for this consistent relation is an advertising effect. Only the rate at which patients asked for advertised drugs, not physicians' response to requests, differed between the 2 settings.

This survey opens an intriguing window on the effects of DTCA on patient-physician interactions in primary care. Our results are consistent both with a dose-response to advertising at 2 different population exposure levels and, most importantly, with increasing industry investment in this marketing technique.^{2,21} If DTCA opens a conversation between patients and physicians, that conversation is likely to end with a prescription, despite frequent physician ambivalence about treatment choice. And the greater the patient's exposure to advertising, the more likely such a conversation will occur.

This article has been peer reviewed.

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Competing interests: Dr. Pan has received speaker fees from Merck Frosst to produce a public service announcement on varicella immunization. None declared for the remaining authors.

Contributors: Drs. Mintzes and Barer contributed to study plan, design, analysis and reporting, Drs. Kravitz, Bassett and Lexchin contributed to data interpretation, review of drafts of the manuscript and, to a lesser extent, study plan, questionnaire and data collection. Drs. Kazanjian and Evans contributed to study design, interpretation and review of the manuscript. Dr. Pan contributed to US components of smidy design and organized and supervised data collection and entry in Sacramento. He also reviewed the manuscript. Dr. Marion contributed to the analysis plan and

interpretation and to subsequent discussion of these components and reviewed the manuscript. All authors gave final approval of the version to be published.

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This is **Exhibit C** referred to in the Affidavit of **Stephen Walter** sworn before me this _______ day of May, 2007.

A Commissioner, etc.

Appendix C: Copy of transcript from FDA heading (interchange between Drs Temple and Mintzes)

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approved by our IRB with an expedited review. And looking into patient financial records probably would have slowed down that process immensely.

DR. PITTS: But what percent of the overall care is indigent are?

DR. SCHULTZ: I would estimate greater than 50 percent, probably less than 70. And it's changed a lot from 1999 until now although I'm not still there.

DR. TEMPLE: This is for Dr. Mintzes. The -- your slides aren't numbered -- the critical slide, it seemed to me, that led to one of your conclusions was the one that gave physician confidence in treatment choice. Can you say a little bit more about what was asked there?

The heading says the medicine was judged to be a possible or unlikely choice versus a likely choice for other similar patients. And in both Sacramento and Vancouver, even where the patient didn't request the treatment, they thought 12 to 13 percent of their treatments were in that category, which makes you ask why did they prescribe it.

And then what did they -- do you have any idea what they meant when they said it wasn't a good choice? Was that a cost consideration or did they

actually give a person a drug they shouldn't have gotten? And admitted it? What was going on there?

DR. MINTZES: Okay, what we were -- I mean the question that they answered was how likely would you be to prescribe the same drug to another similar patient with the same health condition. And they could check off very likely, probably, or unlikely.

So we were -- and that was predetermined that we wanted to look at the proportions that were very likely versus the possibly and unlikely. And what we were trying to get at was the confidence in treatment choice. Or whether the fact that the patient had requested the drug would have shifted the product that the physician prescribed as compared to what they might normally prescribe.

You couldn't -- you know if you asked the physician directly was, you know, how necessary was this prescription, they are legally responsible for the prescription. They're not going to answer that question -- or they're not likely to answer that question honestly. So it was trying to get at it.

And, of course, in some cases, you know, so in terms of the drugs that the patient did not request, in some cases clearly the physician felt that there was something different about the situation with

1	this patient that they would not have prescribed the
2	same thing to another patient.
3	DR. TEMPLE: Okay, so no implied
4	inappropriateness. It was just this was an unusual
5	patient.
6	DR. MINTZES: So, yes, this was an unusual
7	well, who knows.
8	DR. TEMPLE: Okay.
9	DR. MINTZES: I mean this is my guess that
10	this was an unusual patient and so I mean what we were
11	interested in, on its own, if we just looked at the
12	requested advertised drugs and just looked at the
13	answer to that question, it would have said nothing.
14	I mean what we were interested in was
15	looking at how it compared for those particular
16	prescriptions compared to other newly initiated
17	prescriptions by the same physicians.
18	DR. TEMPLE: But you have no sense whether
19	they meant I gave him an ace inhibitor because he
20	asked for it but I would have used a diuretic or I
21	gave him something expensive and branded whereas
22	ordinarily I would said use a generic? Or just what
23	was it that they were saying was different about this
24	from what they would usually give?

NEAL R. GROSS
COURT REPORTERS AND TRANSCRIBERS

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My presumption is they are not telling you

1 I gave the person a drug the person didn't need. 2 DR. MINTZES: Yes, they're not saying 3 that. DR. 4 TEMPLE: So they must have meant 5 something else by that. 6 DR. MINTZES: I think it was the choice of 7 treatments really. So sometimes, I mean there was -the questionnaire did have a place for comments on the 8 9 bottom. But the physicians tended to comment more when they had refused a requested medicine. And had 10 11 prescribed something else. 12 And there were the occasional comments that say Allegra was on formulary, Claritin wasn't, 13 14 for instance as a reason. Or that -- I mean some --15 they also stated what they had prescribed, what else they had done if somebody had requested a drug and 16 17 they had refused. 18 And sometimes they had prescribed something else that was in the same class. Sometimes 19 20 they had prescribed, you know, in some cases, a person 21 would come in for a -had requested hormone 22 replacement therapy. And the doctor had prescribed an antidepressant, for instance. So it was quite a 23 24 different -- a shift in terms of classes.

NEAL R. GROSS

I guess for the next survey,

DR. TEMPLE:

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181181 that one should have a why after it. 1 2 DR. MINTZES: A why? Yes. MR. TROY: Dr. Dubois, I thought you did a 3 -- your study did a really good job of showing where 4 5 as consensus there was, you put it, how DTC 6 advertising reduced the variability. And you portrayed that as a good thing. 7 Then towards the end, you said, "Well, it 8 9 looks like we have to go class by class," and you suggested that where there is evidence of sort of a 10 11 lack of consensus, then maybe we need to treat that or 12 we, if we could, somewhat differently. And I was wondering what the basis was for 13 14 your conclusions about drugs in which there is sort of 15 less consensus, is it only the bar with respect to COX-2 inhibitors because that's the only one that 16 17 there seems to be a fair amount of variation. And you 18 said that was a new product. 19 Was there something else that I'm missing 20 about what the different classes of drugs were that 21 lead you to the conclusion that you need two different 22

sort of approaches?

DR. DUBOIS: Let me answer the question by sort of taking a side step. It wasn't that the COX-2 inhibitors was the linchpin that told me what to do

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