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THE FEDERAL TRADE COMMISSION PRESENTS:

HEALTH CARE AND

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1 But first, Bill Kovacic.

2 MR. KOVACIC: I want to start this morning by
3 thanking all of our participants for this two-day
4 program, and indeed our participants yesterday for

1 in this area.

2 Let me start by looking back a bit. As all of
3 you are familiar, the U.S. competition policy system is
4 distinctive for the open-ended nature of the substantive
5 commands. We don't have industry-by-industry
6 competition policy commands. We have very broad,
7 generic declarations of authority, which place an
8 absolute premium on the capacity of enforcement agencies
9 and courts to adapt general principles and apply them
10 sensibly in specific industry context.

11 In 1969, the American Bar Association report on
12 the Federal Trade Commission, which in many ways is the
13 modern watershed for the development of the Commission
14 of the current era, suggested that the FTC had a unique
15 role to play in applying competition policy principles
16 to what the ABA called areas where issues of
17 anticompetitive effects turn essentially on complex
18 economic analysis.

19 Put another way, what the ABA was really telling
20 the FTC to do is to take on the hard problems, to take
21 on the hardest problems of competition policy and to
22 devote its attention and effort to this area.

23 I would suggest to you in the now nearly 90-year
24 history of this institution, the modern health care
25 program is the single greatest achievement in the

1 competition policy field of this agency. Going back to
2 the early 1970s where our legislative overseers strongly
3 suggested that we take greater interest in issues
4 associated with increases in health care costs, to the
5 prosecution of the American Medical Association case,
6 the complaint filed in 1975. Path-breaking work
7 involving mergers in the HCA case in the 1980s, a
8 plethora of studies in the field.

9 I would suggest that this area more than any
10 other, and I'll make the assertion quite strongly, more
11 than any other in the 88-year history of this
12 institution has been the flagship program. This has
13 been the best possible synthesis of our economic and
14 legal learning, and, I think, our greatest success to
15 date in taking on very difficult problems in an
16 extraordinarily complex competition policy area.

17 In short, if I were challenged to offer one
18 respect in which the FTC has truly fulfilled the destiny
19 that Congress had in mind in 1914, I would advance our
20 work in the health care area as being the best example.

21 What's the challenge looking ahead? The
22 challenge is to make sure that our policy-making
23 properly reflects marketplace realities. In this field
24 in particular, to ensure that both price and nonprice
25 attributes are given proper effect in the application of

1 competition policy rules.

2 I think this has a major implication for how we
3 use our resources, and it involves a continuing change
4 in the way in which we emphasize litigation and
5 nonlitigation application of our resources. I think the
6 basic implication is that we are going to be spending,
7 as time goes by, more and more of our resources in what
8 I would call competition policy R&D.

9 Back in my former life when I was an
10 irresponsible academic and I enjoyed criticizing the
11 agencies, I was fond of focusing on measuring outputs,
12 such as cases. When I would show up at CLE programs and
13 make smart-mouthed comments about what the agencies were
14 doing, I gravitated towards discussing cases. Cases,
15 after all, are what academics tend to teach in this
16 field.

17 I've come to this job now, over the past 15
18 months, with a much greater sense of humility and
19 appreciation for the extent to which the capacity to do
20 good policy-making requires a basic investment in
21 research and development. In other words, if we were a
22 firm, I think we'll have to see ourselves spending more
23 and more time simply on what a firm would designate as
24 our R&D.

25 In short, the norms by which we ought to be

1 measured and evaluated over time include a greater
2 willingness to invest in activities that increase our
3 knowledge base.

4 Let me finish by simply identifying two key
5 areas in which this type of investment, I think,
6 increasingly is going to characterize our work: The
7 first is this workshop. This is becoming an
8 indispensable tool for staying attuned to the
9 developments for academic scholarship in industry
10 developments that are indispensable to our capacity to
11 make good policy. To be willing on a regular basis in
12 depth to hear from a variety of different constituencies
13 about what's taking place in the marketplace.

14 Again, I salute David for assembling an
15 absolutely superb vehicle for doing this, and to
16 anticipate that this is something of which we'll do more
17 in the future.

18 The second is an expanded research agenda,
19 really of two types: The first is the willingness to do
20 substantial empirical studies. David Scheffman has
21 developed a wonderful internal empirical agenda, and
22 you're familiar with outputs such as our generic drug
23 study. The generic drug study required us to devote
24 some of our best resources to gathering data and
25 analyzing them. I think the result was an absolutely

1 superb report, but again, measured by the standards I
2 would have applied in my former life, it doesn't
3 generate a case, it generates a study. But a study, I
4 think, again, that's crucial to our capacity to do good
5 policy work in the future.

6 A second is our willingness to do
7 retrospectives, looking at past cases. If the antitrust
8 process itself was a form of health care system, it's a
9 relatively remarkable one. For the most part, agencies
10 have devoted relatively little of their resources to
11 evaluating past effects. It's like a hospital that does
12 surgery and never goes back and talks to the patients,
13 but assumes that they're doing well.

14 As my colleagues described yesterday, especially
15 with respect to hospital mergers, we're simply willing
16 to spend now and are spending more resources to go back
17 and look at actual consequences of consummated
18 transactions. And if those consequences are benign or
19 procompetitive, we'll make that known. If there are
20 problems, we'll look further.

21 But making this kind of after-the-fact
22 assessment, a core indispensable routine element of what
23 we do, day in and day out, I think, becomes an
24 increasing important element of the competition policy
25 agenda looking ahead.

1 It's useful to pause for a minute, I think, and
2 look and contemplate what's the meaning of even the
3 title of the workshop. This is a workshop on
4 competition law and competition policy in health care
5 markets. It's useful to try to think, how is that
6 different? How might that be different from a workshop
7 on antitrust law, and antitrust policy?

8 I would suggest that the difference between
9 those two might be useful to the FTC in trying to use a
10 compass and formulate what its future role in this

1 So, inward-looking, and then we had a number of
2 those issues explored yesterday, complicated issue, how
3 is the most appropriate way to apply antitrust doctrine
4 to this sector?

5 The second component of a competition policy is
6 very much outward-looking. It's a recognition that
7 competition or that antitrust policy and antitrust law
8 is simply one component of a broader health care system.
9 So the outward-looking component would try to reconcile
10 the government's role as an antitrust enforcer, the
11 government's role as the largest purchaser of health
12 care services in the country, and the government's role
13 both at the state and federal level as a regulator of
14 health care services, with the goal of greater
15 intrasystem rationality.

16 Thinking about how does the role of purchasing,
17 how does the role of regulation affect competition in
18 health care markets and trying to think of a competition
19 policy that coordinates those various functions where
20 antitrust law is one component, although a very
21 important component of a broader system.

22 Within that role, I think the FTC could play a
23 very important role, and is probably uniquely situated
24 to engage in a variety of inter-agency type coordination
25 to remind the government in its actions and various
26 capacity of the impacts of different policies upon

1 competition. That's sort of what I think of a
2 competition policy.

3 That being said, and Howard Beales from the
4 consumer protection bureau of the agency was up here
5 talking yesterday, I probably have violated norms of
6 consumer protection in the title of this talk, because
7 this is probably not an empirical look at competition
8 policy, because realistically an empirical look at
9 competition policy, no matter how long or how hard I
10 looked under the microscope, might not reveal very much
11 because I don't think we have a very sophisticated or
12 networked competition policy.

13 A probably fairer title for my talk would be an
14 empirical perspective on antitrust litigation, and what
15 we're really going to be looking at and talking about
16 today is the role of private and public antitrust
17 litigation in the health care sector over the past 15
18 years, although I promise at the end of it to come back
19 to this theme of competition policy and try to
20 coordinate or at least think about what the empirical
21 findings suggest in the goal of establishing the
22 competition policy.

23 Attributions at the fore are appropriate, this

1 is a joint undertaking with Bill Sage at Columbia Law
2 School who is equally responsible for the insights and
3 the blunders that we may have accomplished together and
4 it's supported by a generous grant by the Robert Wood
5 Johnson Foundation as part of their investigator award
6 program in health policy research.

7 This is just going to be kind of an infomercial,
8 right, to try to give you a flavor of broader things.
9 I'm not going to try to exhaust the resources, but if
10 you're interested in some of the issues that are talked
11 about, there are two recent publications that are
12 helpful: The first is Antitrust and Health Care Quality
13 in the Courts in the Columbia Law Review. So, if you
14 want all of the tables, all of the data, the discussions
15 of the methodology, that's where you would find it.

16 There's a second piece entitled The Copernican
17 View of Health Care Antitrust that's coming out
18 hopefully later this month in an issue of Law and
19 Contemporary Problems, and that's our effort to try to
20 take the empirical work and talk about developing this
21 integrated competition policy for health care markets.

22 People here would probably be interested in that
23 issue more broadly. It's put together by Clark Havighurst
24 at Duke Law School and looks at the question of whether
25 the health care revolution is over, and looks at the rise
26 of managed care, the stall of managed care and the potential fall of

1 managed care from a variety of perspectives. So, people interested
2 in the issues of this workshop would probably also find that
3 symposium helpful.

4 What do I mean by empirical? This is, again,
5 trying to vet out the possible misconceptions of the
6 title of the talk. The economists in here are probably expecting me
7 to say something very different when the
8 title promises an empirical perspective of antitrust
9 litigation.

10 So, what is it? It's a detailed study of health
11 care antitrust enforcement. And why do that? The
12 objective is really to try to assess judicial capacity
13 to assess quality in nonprice concerns. If we're going
14 to have a competition policy, we're going to have a
15 realistic goal for antitrust law, we also have to have a
16 realistic objective of how the courts can handle these
17 types of issues and how far antitrust law and doctrine
18 can be stretched to accommodate various quality in
19 nonprice concerns.

20 What is it not? It is not an economic study of
21 health care markets themselves, as an economist or an
22 econometrician might do, although that type of research
23 is vitally important in defining both an appropriate

1 antitrust policy and competition policy.

2 One caveat, however, at the very beginning of
3 our study, we were very interested in trying to
4 determine the extent to which courts use empirical
5 studies of health care markets, economic research, the
6 health services research literature, in resolving
7 typical antitrust litigation problems. So, in the back
8 of your mind, kind of have this open question in the
9 past 15 years, what has been the role within litigation
10 of this type of more economic empirical studies, and
11 we'll shed some light on that question before we're
12 done.

13 Again, a summary of the study objectives, more
14 particularly it's to describe medical antitrust

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1 out of those, we reduced it to a data base of about 539
2 opinions concerned to be relevant. Obviously any one
3 dispute can rise to a number of different numbers of
4 opinion, so if you reduce that down, you have slightly
5 over 400 separate disputes dealing with medical
6 antitrust litigation in the 15-year period of the study.

7 You get the typical kind of pyramid that you
8 would expect. The Supreme Court sitting on top doing a
9 small number of cases, one percent over the 15-year
10 period. You then have the nice kind of pyramid of about
11 one-third of the cases being federal courts of appeals
12 decisions, and about two-thirds of the opinions
13 happening down in the trenches with the district courts.

14 We coded a vast number of things, including what
15 are the allegations, what's the time to legal analysis,
16 and for that, again, I would refer you to the Columbia
17 Law Review article. Here I just want to simply try to
18 focus on business conduct at issue. Who is suing whom?
19 What are the kind of activities in the health care
20 sector over the 15-year period that is generating
21 opinions? In contrast, the sort of category of all
22 opinions inclusive of private litigation, with the
23 activities of the public enforcers.

24 Probably the most striking thing, if you look at
25 the first two lines, staff privilege cases, and

1 exclusive contracting cases, in the private setting,
2 account for almost two-thirds of the cases, right?
3 Anybody who has already added up the totals and find out
4 they go larger than 100, not uncommon you have multiple
5 coding possibilities. These aren't exclusive, you can

1 portion of the public enforcement activity, and this is
2 inclusive of the FTC, the DOJ and state attorney
3 generals coded in the public category, has been merger
4 activity. You had a number of discussions yesterday
5 about the nature of the merger cases and I'll have some
6 things to add to that subsequently in the presentation.

7 Other than that, on the public side, you see a
8 fairly even distribution, all right, of challenging a
9 wide variety of aspects of the health care sector, and
10 in taking Bill's comment to heart, we'll also talk in a
11 minute about how does one interpret a small number of
12 public cases in light of the larger enforcement agency
13 agenda, any impact that they may have in relationship to
14 private cases.

15 Other striking factors, if you go down to the
16 insurance and managed care category of cases, the
17 network participation, joint contracting, unilateral
18 contracting terms, you find out that all told, they
19 reflect only about 17 percent of the allegations.
20 Again, you kind of have to calibrate how much is
21 happening on the public side? Huge amount within
22 physician hospital relationships, relatively small
23 amount of activity happening in the insurance sector and
24 in the managed care sector in terms of private antitrust
25 litigation.

1 Then there's a component here of what we call
2 information type cases, gathering together a variety of
3 things that say, what's the role of information in
4 health care markets, that we also tried to isolate and
5 to track.

6 Now, obviously you can try to break this down by
7 periods, look at each five-year period separately and
8 see if you have any interesting insights. Interestingly
9 enough, the aggregate number of cases doesn't change
10 substantially over the period. So, you don't have
11 substantial increase or decrease in the amount of
12 antitrust private litigation. You have again staff
13 privileges and exclusive contracting cases being the
14 biggest categories. You have a small decline in staff
15 privileges cases in the last period.

16 You know, in 1986 you had the Health Care
17 Quality Improvement Act that provided limited federal
18 immunity for certain forms of staff privileges. You
19 might be able to attribute the decrease to that, but
20 then you would have to say, why does it take ten years
21 for a federal law to begin to have marginal effects?
22 And you can engage in story telling on either side of
23 that question.

24 The last part of the study period, exclusive
25 contracting cases, exceeds the number of staff

1 privileges cases as the largest category. Again,
2 interestingly enough, you see an increase in merger
3 activity, at least as represented in actual litigation.

4 If you now go down to the information cases, you
5 actually see a decrease in the private credentialing and
6 accreditation cases, which I find interesting, and I
7 find that as a sign of saying that that war has
8 basically been won. People recognize the value of
9 information, a lot of plaintiffs no longer try to argue
10 with various credentialing agencies or other forms of
11 standard-setting within the industry, at least on
12 antitrust grounds.

1 right? Not that the plaintiff ultimately wins in the
2 end, but at least they have stalled the defeat that they
3 might have suffered ultimately. Affirmances of appeals
4 by defendants or reversals on appeals by plaintiffs are
5 also substantial outcomes for plaintiffs. All told,
6 they get substantial outcomes in only 15 percent of the
7 cases that they bring. Defendants winning about
8 two-thirds and about 20 percent of the cases being kind
9 of neutral in terms of the disposition of the ultimate
10 resolution of the dispute.

11 So, the private lesson is, unsuccessful
12 plaintiffs. What about the public side, right? You
13 might sort of say, wow, in comparison to the private litigants, at
14 least the public litigants are much more successful. You see a
15 success rate of about equal number
16 of wins and losses on the way that we have sort of subjectively
17 categorized it.

18 If you now go down to substantial outcomes for
19 defendants in the public category and remove all of the
20 losses in the hospital merger cases, you would have a
21 substantial inflation in the government win rate, and so
22 those merger cases, at least in the 15-year time frame
23 that we're looking at, drive the government win rate
24 down from sort of historic highs of the kind of high
25 '70s, even if you go back to 1960s, 80 percent win rates

1 down to something closer to 50/50.

2 Again, you can try to break that down by forms
3 of conduct. You tell some stories here that the
4 antitrust lawyers in the room would not find surprising,
5 staff privileges cases are the dogs of the dogs in terms
6 of trying to win for plaintiffs with the lowest rates,
7 exclusive contracting hitting closer to the mean of what
8 the average is.

9 The other category, remember other now is
10 anything that's not staff privilege or exclusive
11 contracting, so that's all of the insurance cases, all
12 of the managed care, all of the things dealing with
13 medical devices and pharmaceuticals, higher win rate,
14 relatively speaking for plaintiffs, although
15 substantially lower in terms of what happens in terms of
16 outcomes for defendants.

17 Again, sort of gives you a flavor of who is
18 suing who and what some of the outcomes are.

19 I can sort of conclude this descriptive
20 component and then we're going to shift over to talking
21 about quality of care and quality of nonprice
22 competition, although there are a couple of things that
23 sort of encapsulate what I've already said.

24 Litigation is dominated by hospital/physician
25 relations, right? That's kind of disconcerting for

1 those of you who expect to use private antitrust litigation
2 as a vehicle for policy making. It's not effective, at
3 least for the bulk of the cases.

4 Managed care reflects a small minority of
5 litigated cases by comparison, and plaintiffs lose no
6 matter how you measure that, although the public
7 concerns and win rate is higher.

8 Interestingly, again, and it sort of questions
9 how do you make the numbers? If you wanted to say that,
10 boy, over a 15-year period, the government has only
11 brought, you know, some 20 or 30 cases, what are they
12 doing in terms of health care litigation? They are only
13 a small part of the picture, right, in relationship to
14 the private cases.

15 It raises interesting questions about who sets
16 antitrust law, right? Is antitrust law being driven by
17 private or public entities? Does bad case law on one
18 side of the private/public divide influence the outcomes
19 on the other side of the divide? Is one of the challenges public

15

1 public antitrust enforcement.

2 Here are the caveats that I think are
3 appropriate and correspond to some of the things that
4 Bill was talking about: Judicial opinions only reflect
5 a small part of what an agency does, right? So it's
6 unfair to try to generalize too much about public
7 antitrust enforcement roles, simply by looking at

1 forum of private litigation.

2 Kind of shifting gears now out of the
3 descriptive information of the private litigation into
4 this discussion of quality and nonprice competition.
5 It's hard, and a number of these things were reflected
6 in the discussion we had yesterday, a number of them I'm
7 sure will persist in the panel discussions today. What
8 do we mean by quality? How do we know it when we see
9 it? How is an antitrust or an enforcement agency
10 supposed to prosecute or regulate in terms of protecting
11 quality?

12 The first thing I think you have to let go of is
13 thinking that there's a uniform view or that quality
14 means one thing. The reality is, and if you look at the
15 coding instrument, which was multiple categories,
16 quality means many different things in many different
17 contexts, you just have to get comfortable with that and
18 therefore try to think about the many different meanings
19 of quality.

20 Underlying a lot of this discussion are
21 paradigmatic, you ask a health care professional what
22 quality means, you get a fairly objective absolutist
23 interpretation. You ask an antitrust lawyer and an
24 economist what quality means, you get a very different
25 understanding paradigmatically about what quality is.

1 I like sort of the distinction of saying that a
2 lot of health care professionals view quality as
3 something apart from competition, really separate from
4 competition, whereas the traditional antitrust response
5 and economic response is to say no, quality is a part of
6 a competitive process, and that is one way to get a
7 handle on sort of the conflicts that you often have
8 between health care professionals and antitrust
9 enforcers about the meaning of quality in nonprice
10 competition.

11 Health services research literature provides a
12 different window on the world, right? These are the
13 people that are out there and make their lives studying
14 the health care system in a very quantitative fashion
15 trying to answer basic questions about what are the
16 effects of various practices, organizational forums, and
17 processes? In the health services research literature,
18 you basically break down quality into the structure and
19 process outcome paradigm, and if you come from the
20 University of Michigan, you have to attribute that to
21 Donabedian who was at the Public Health School at the University of
22 Michigan for years and years.

23 That provides a whole different method of trying
24 to understand quality. You measure the accreditation,

1 the ownership, the physical facilities. If you're
2 talking about the structure components and the process
3 components, you look at what tests are ordered,
4 malpractice history, preventative services and outcomes.
5 You say, well, what's the actual affect on morbidity,
6 mortality? You have surveys, you have consumer
7 rankings.

8 So, there's a rich area of literature out there
9 that might measure quality in a quantitative way that

1 One thing we did in the survey instrument or the
2 coding instrument is try to code what judges think about
3 the effects of competition. What are their beliefs
4 about the role of competition. Again, these are all in
5 health care cases, variously defined. What we found is
6 sort of two lessons you might take home: First is that
7 most of the opinions don't expressly articulate views,
8 right? So what we have here is 539 opinions in the
9 background and we're generating things at the highest of
10 sort of 58, 38, 7 coding things of courts actually
11 expressly considering these considerations.

12 Of the courts that do express a particular view,
13 orthodox beliefs dominate unorthodox beliefs. And by
14 that I mean most courts believe that what most antitrust
15 enforcers believe, that competition decreases prices,
16 that competition decreases cost and that competition
17 will in various ways increase quality, although what do
18 we mean by quality? A more complicated question.

19 The unorthodox beliefs are out there, but
20 they're really in a handful of cases. Six coded entries
21 saying that competition will increase prices. Seven
22 coded entries saying that competition will increase
23 costs. That sorts of the medical arms race scenario
24 that was discussed yesterday. Three entries saying that
25 competition will decrease quality, which is really kind

1 of the larger policy issue and question at the fore of
2 thinking about managed care in sort of the new
3 millennium.

4 All right, so that's interesting. To say the
5 courts at least express a view about quality, they adopt
6 orthodox views and that the unorthodox views, despite
7 the sort of losing trend in the merger cases, actually
8 represent a minority view.

9 Other interesting sort of findings from the
10 antitrust lawyers' perspective, the whole sort of set of
11 Goldfarb era concerns. You know, that trepidation of
12 approaching the profession of antitrust rules, that
13 professions are different, you need different standards
14 and you have all of these unique social and professional
15 concerns, barely get lip service, all right? So at
16 least in the sort of time frame that we looked at, 1985
17 to 1999, Goldfarb era concerns get very little
18 attention.

19 One caveat there is at the end of our study
20 period, what happens? We have California Dental
21 Association decided by the Supreme Court, California
22 Dental Association for the first time probably since
23 Goldfarb was decided in the 1970s, raises the specter of
24 Goldfarb era concerns again, and if that's going to take
25 root within district courts or appellate courts, we

1 don't have a study window that allows us to answer that
2 question.

3 All right. Overview on the quality
4 characteristics. This is again going to give you a sort

1 distribution, although I'll go through a series of
2 slides that gives you a more particular view of the
3 entries that we considered.

4 If you're now looking at clinical structure, and
5 again, remember, the end back there is 539 cases, right?
6 So, this is really saying that these particular sets of
7 issues are raised in really only a small handful of
8 cases in practice.

9 If you want sort of two other numbers that are
10 actually quite helpful: Thirty-six percent of all
11 private cases raise at least one quality coded factor,
12 all right, so you sort of say, in one-third of the
13 private cases, at least one of the issues that we're
14 coding for the many issues on quality, were addressed by
15 the code, right? Which means that two-thirds of the
16 private cases don't raise any of the quality factors
17 that we look at.

18 If you look at the public side, interestingly
19 enough, 71 percent of the public cases raised one of the
20 factors relevant within our sort of quality nonprice
21 coding instrument. So there's a greater tendency
22 amongst the public cases to be paying attention to these
23 various concerns than there are in the private cases.

24 Structural components, easier to understand why
25 courts are trying to focus upon those and use those.

1 You can look at these things, I can try to measure them,
2 and I can imagine theories one way or the other on why
3 these factors might be able to increase quality and I
4 might be able to think of the effect of competition and
5 various levels of restraints in trade on these, all
6 right.

7 So, it's the qualification of physicians,
8 adequacy of staffing, continuity of care, adequacy of
9 facilities, private accreditation, advanced technology.
10 You know, these are not brain science, or sort of rocket
11 science or brain surgery, these are bread and butter
12 things that one would think if one were worried about
13 quality in competition, you would have discussions
14 related to these.

15 Some of them do occur, which I guess is an
16 important finding, but not in a very sophisticated
17 fashion, and not very often. Switch over to clinical
18 process, we can tell a couple of different stories from
19 these numbers. The first is, guess what wins?
20 Unspecified process or quality concerns, right? When
21 courts talk about quality it's usually done in an
22 abstract level. There's a lot of hand waving, not a lot
23 of efforts to try to be specific, and therefore on all
24 the kind wastebasket categories seem to win in terms of
25 the number of tabulations. This is not surprising.

1 Malpractice history gets 25 coded entries.
2 Almost exclusively in the staff privileges cases that
3 you might expect. And ironically, you know, people sort
4 of well-versed in health policy and health law know that
5 the malpractice history probably has very little
6 relevance or correlation to actual quality, right? So,
7 if you're looking for a measure of quality, the one the
8 courts seem to latch on here, malpractice history,
9 actually is not a very reliable factor.

10 Significantly, potential for clinical
11 improvement is acknowledged in a small handful of cases,
12 and I find that promising. And these are cases that
13 talk about particular doctors or practices having unique
14 approach to a typical type of medical problem, and
15 underlying the protection of clinical innovation is not
16 just simply concern for innovation but an underlying
17 protection of choice, and we'll get to choice more
18 directly in the market-level characteristics.

19 If you look at the losers here, rankings in
20 quality surveys, outcome statistics. These are the gold
21 standards of the health services research literature,
22 right? This is what all the professionals will say, how
23 do you measure quality? Talk about quality? Think
about quality? What do I nel3ewo cnow thomarke ere-6k anre, rank

1 instrument in terms of what you find in judicial
2 opinions. All right?

3 So, one significant finding of our analysis
4 and our study, courts just don't deal with health
5 services research literature. And what does that mean?
6 That means that antitrust lawyers are not calling
7 them as expert witnesses, are not trying to develop
8 theories of the case that rely on that type of evidence,
9 and rather rely upon these vague kind of abstract
10 notions of unspecified quality concerns and hand waving
11 when they deal with these issues.

12 I will go through this slide fairly quickly.
13 General reputation for quality can have two
14 interpretations: One, again, is further support for
15 this kind of abstract notion of quality, trumping any
16 specific notions, that's supported by the other category
17 winning ten coded entries.

18 There's also a different story you can tell.
19 Reputation in malpractice history are at least possible
20 economic indicators of quality upon performance.
21 Malpractice exposure, whether or not it's correlated
22 with quality is correlated with potential liability
23 exposure. General reputation for quality can be
24 translated into notions of good will within a business
25 school setting.

1 And one can say here that the things that are
2 more likely to register on the antitrust metric of these
3 opinions are quality considerations that can be
4 translated into an economic parlance such as improving
5 good will and reducing malpractice exposure. And one
6 can say that courts are receptive to efforts, marginally

1 demonstrated that competence.

2 If you look at information, you have a smaller
3 number of cases, but a sensitivity to the role and
4 importance of information in making markets work
5 effectively. And the thing about R&D innovation, small
6 number, right? And that's kind of disappointing, if you
7 think of a dynamic efficiency perspective, if you review
8 innovation as an important nonprice concern or attribute
9 of markets, courts seem to be less significant or less
10 attentive to innovation as a separate concern.

11 Some preliminary conclusions, then: What can we
12 say about some of the quality? One interesting thing is
13 really that there is a return to orthodoxy here, and
14 that orthodox beliefs trump the unorthodox beliefs. Why
15 is that relevant? I think from that and from sort of
16 the other things that we get from our instrument, no
17 matter how much of a black eye the public enforcement
18 agency has suffered from the hospital merger cases,
19 they're an anomaly, right?

20 The same theories of the case that underlie the
21 hospital mergers hasn't bled off into the other areas of
22 antitrust law, right? So you can sort of view them as
23 idiosyncratic, isolated incidents of judicial skepticism
24 about the effects of competition, and I actually find it
25 quite interesting that the same paradigm that motivated

1 the courts in those cases has not seemed to influence
2 judicial decision making in a wide range of other
3 private and even public antitrust enforcements, and I
4 think that's significant.

5 There's a tension in these opinions, right? The
6 tension is sort of back to this idea that there's many
7 meanings of quality. There's a tension between courts
8 as they try to view quality either as part of
9 competition or apart from competition, and that tension
10 is probably best illustrated between the staff privilege
11 cases and the exclusive contracting cases.

12 All right, remember plaintiffs lose both of
13 these things, but if you look at how they deal with
14 quality concerns, there's a very different temperaments
15 in the opinions. In the staff privileges cases, they
16 view quality as a constraint upon competition. Similar
17 to licensing, similar to malpractice histories, similar
18 to self regulatory traditions within health care and are
19 deferring to the assessments of quality of these other
20 benchmarks, right?

21 So, they divorce quality from its sort of
22 antitrust concern about competition, and treat this
23 whole range of issues as apart from competition.

24 The exclusive contracting cases are the exact
25 opposite. In the exclusive contracting cases, which are

1 again about one-third of the sample, courts expressly
2 view quality, and now we're talking primarily about the
3 quality of the hospital, vis-a-vis a particular set of
 anesthesiologists, or other sort of doctor shop as a

1 your clients, how do you articulate them better?
2 Because you're not doing a very good job, or at least
3 the courts are not being receptive to those arguments
4 and there might be sort of areas to mind in bringing new
5 resources and resources to bear in the context of
6 litigation.

7 Courts are more likely to employ traditional
8 antitrust heuristics of decision making, right? This is
9 what we pick up in any antitrust textbook, the value of
10 choice, right? The value of information, the value of
11 innovation. By innovation I'm concerned here not just
12 simply about technological innovation but forms of
13 organizational innovation. And one can view managed
14 care simply as a form of organizational innovation and a
15 lot of the change in the health care industry in the
16 last 15 years in terms of innovations in terms of
17 organizational form.

18 Much higher chance that if you can get a theory
19 of the case that fits into one of those heuristics, the
20 courts will respond, than if you're trying to get the
21 court to sort of wander further out on the boundaries of
22 nonprice and quality competition. And kind of remind
23 you that antitrust law, again, sort of from the private
24 perspective has played only a minor role in addressing
25 quality-related concerns in managed care in the

1 imposes a challenge most of the public enforcement
2 agencies and to the courts to say, can this sort of set
3 of rules that govern the economy be applied
4 appropriately in the context of sort of basic antitrust
5 litigation.

6 So far, I would say the performance has not been
7 stellar. I think you can point to sort of small trends
8 and instances that might be able to be reproduced and
9 emulated, but a lot of work still needs to be done to
10 sort of rethink antitrust law in a way that can
11 appropriately be applied in a lot of medical settings.

12 If I'm now kind of changing hats, right, and
13 going from the inward-looking sort of how do I revise
14 antitrust law to the outward-looking of how do we have
15 antitrust law work in conjunction with a wide variety of
16 other sort of government actors, regulation purchasing
17 antitrust enforcement, one of the things that we argue
18 for in the Copernican piece that comes out in long-term
19 temporary problems is the need to get away from the

1 I'll highlight a couple parts of interesting
2 doctrinal concerns that a competition policy is going to
 have to wrestle with in the future. One is the

1 proposition that we should actually get rid of the State
2 Action Doctrine and subject the state regulations to
3 forms of substantive antitrust scrutiny in similar ways
4 that we would do with private regulation and private
5 self regulation. So I think we can rethink the
6 parameters of the State Action Doctrine in ways to get a
7 more coherent competition policy.

8 As Professor Brewbaker suggested yesterday,
9 there's always a contention in health care markets

1 cite the GPO contract.

2 The idea is that by pooling the purchases, they
3 can negotiate a lower price than an individual hospital
4 can on its own. There's also other supposed cost
5 savings that they can provide hospitals. For example,
6 the hospitals all don't have to negotiate themselves
7 with every manufacturer, and the same time,
8 manufacturers don't have to do some of the marketing and
9 sales to reach every single hospital by virtue of the
10 GPO being in existence.

11 So, after the GPO negotiates the contract and
12 the hospitals -- and some of them, they're primarily
13 voluntary relationships. So, just because they're
14 negotiating on behalf of several hundred hospitals
15 doesn't mean those hospitals are going to buy everything
16 based on that contract. But after they do buy
17 purchases, the vendors will pay a portion of the sales
18 back to the GPO as administrative fees. This is how the
19 GPOs pay for their operating expenses.

1 the hospitals that they negotiate for. Not always, in
2 some cases there are individual independent investors
3 that own the GPOs, but often hospitals and other health
4 care organizations actually own the GPO itself.

5 So, those are the two basic things. They are
6 contract negotiators, they don't buy or sell on their
7 own, and they charge administrative fees, and that's how
8 they make their money. But beyond that, they really
9 vary a great deal in how they do that, and whether they
10 do it nationally or regionally, what other services
11 besides contract negotiation they offer, and while they
12 are primarily private for-profit companies, whether they
13 are again owned by member hospitals or not.

14 Just for a sense of the size, the GPOs in our
15 study basically reported that using their contracts, the
16 generated sales are between \$1 billion and \$14 billion,
17 so even though the relationship is voluntary, there's a
18 lot of money going through these contracts.

19 Then the next two things I am going to say are
20 things we didn't really talk about in our study or look
21 at, but just background information. There are
22 guidelines put out by the Department of Justice and
23 Federal Trade Commission that help GPOs gauge whether or
24 not they might be an antitrust concern. Basically just
25 because you meet the two tests that are included in the

1 guidelines doesn't mean that you are not a concern.
2 There could be extraordinary circumstances which make
3 you a concern.

4 Just because you don't meet the test doesn't
5 mean that you are also a problem. But basically the
6 first test looks at whether there's enough purchasing
7 going through the GPO that it can effectively exercise
8 increased market power, and drive prices below the
9 competitive level. The second one is really looking at

1 they have to disclose in writing to each member the
2 amount of money they actually got from the vendors based
3 on the purchases made either by that member or on behalf
4 of that member.

5 So, that's background information. And what we
6 did was a pilot study, and it was done at the request of
7 the Senate Judiciary Committee, Subcommittee on
8 Antitrust. It was a very narrowly focused study. The
 context of the study was that there were concerns that

1 paid when they used a GPO with the price the hospital
2 paid when they bought on their own. Because it turns
3 out most of the 18 hospitals in our study did belong to
4 a GPO but they almost all also bought outside of the GPO
5 contract.

6 That's the first question. The second question
7 was looking at whether they were buying from small
8 manufacturers or not, kind of a representation issue.
9 Basically based on the data that we got, from the 18
10 hospitals, for pacemakers and safety needles, we found
11 that the hospitals using the GPOs did not always get a
12 better price for the member hospitals.

13 When we first looked broadly at anybody
14 everybody, and compared to hospitals that used the GPO,
15 those buying on their own, always got better price for
16 five models of safety needles we compared. They ranged
17 from one to five percent, though. The hospitals using
18 the GPO contract paid one to five percent more. For
19 pacemakers, the ratio was much greater and basically
20 hospitals using the GPO contract for one model paid 25
21 percent less than the other hospitals, and for another
22 model, paid 39 percent more.

23 So, the variation was great, but more than half
24 of the time the GPO, the hospitals using the GPO contract
25 did worse than the hospitals buying on their own in this

1 case.

2 We also looked at all the hospitals and then
3 looked just for large GPOs, and those we defined whose
4 sales are of \$6 billion or more per their contracts.
5 Basically we found the same thing. The hospitals using
6 the large GPO contracts did worse for the five safety
7 needle purchases we could compare and did worse about
8 half the time for the pacemakers.

9 We then looked at the size of the hospital and
10 found that small and medium-sized hospitals were more
11 likely to have price savings with GPOs, using the GPO
12 contract. Basically small hospitals using the GPO
13 contracts, those with 200 or fewer beds always did
14 better, and this is for pacemakers, when they used the
15 GPO contract than those who purchased pacemakers on
16 their own, the small hospitals on their own.

17 Conversely, large hospitals always did better
18 buying on their own, they rarely did better when using
19 the GPO contract.

20 The third comparison that we did was we looked
21 at hospitals using large GPO contracts versus those
22 using small. And we found that it varied by the device.
23 The hospitals using the large GPO basically did better
24 for virtually all those safety needle purchases, but
25 when they bought pacemakers they were less likely to get

1 hospitals, and for other medical surgical supplies and
2 devices between the pacemakers and safety needles.
3 That's it.

4 (Applause.)

5 MR. HYMAN: Thank you very much, JoAnne.

6 We now have a panel on hospital group purchasing
7 organizations, if everyone from the panel could come up.

8 MS. DeSANTI: Good morning. My name is Susan
9 DeSanti, I'm Deputy General Counsel for Policy Studies,
10 and next to me is my colleague, Matthew Bye, who is also
11 in the Policy Studies Shop in the General Counsel's
12 Office.

13 I want to welcome everyone to today's panel and
14 I particularly want to thank our panelists for their
15 time and effort in coming, we very much appreciate
16 having you here, and we think we're going to have a
17 diverse and balanced group of presentations today on
18 hospital group purchasing organizations.

19 I'm going to start by briefly introducing each
20 panelist, moving down the table, and that's the order in
21 which they will make their presentations. Each panelist
22 will make a presentation and then we'll have time for
23 discussion at the end, and I do want to emphasize, David
24 has obviously been keeping the time moving swiftly, and
25 I think will continue to do so. The presentation is

1 President Materials Management at Sentara Health System,
2 an integrated delivery system of hospitals, clinics,
3 nursing homes and managed care insurance markets in
4 Norfolk, Virginia. He has 23 years of materials
5 inventory systems integration project management and
6 solution development experience.

7 Then we move to Bob Burns, who is the James
8 Jugin Kim Professor, and Professor of Health Care
9 Systems in the Wharton School at the University of
10 Pennsylvania. Bob is also a director of the Wharton
11 Center for Health Management and Economics, and Visiting
12 Professor in the Department of Preventative Medicine at
13 the University of Wisconsin School of Medicine.

14 Then we have Cliff Goodman. Cliff is a Senior
15 Scientist at the Lewin Group, a health care policy and
16 management consulting firm based in Falls Church,
17 Virginia. Cliff has more than 20 years of experience
18 working with government industry and nonprofits in
19 health care evaluation.

20 Next to him we have Steve Latham, who is
21 Assistant Professor and Director for The Center for
22 Health Law Policy, Quinnipiac School of Law where he
23 teaches health care business law, business organizations
24 and administrative law. He is also a lecturer at the
25 Yale School of Management where he teaches business

1 ethics.

2 Next to him we have Larry Holden who is the
3 President of the Medical Device Manufacturers
4 Association in Washington, D.C. Prior to joining MDMA,
5 Larry was chief of staff to Congressman Christopher
6 Shays of Connecticut.

7 Finally we have Robert Betz. He is president
8 and CEO of the Health Industry Group Purchasing
9 Association. He has spent more than 20 years
10 representing health care organizations in Washington,
11 D.C. Prior to forming a private health care consulting
12 management and lobbying firm, Robert worked for the
13 American Hospital Association in Washington and the
14 Louisiana Hospital Association in Baton Rouge.

15 With that we will get started with our
16 presentations, and you may go first.

17 MR. CLARK: I am pleased to be here with you
18 today, ladies and gentlemen.

19 As was mentioned, I'm Bruce Clark, I'm here on
20 behalf of the American Hospital Association and
21 represent specifically Intermountain Health Care, which
22 is my employer. We're an integrated delivery system
23 operating in Utah and Idaho. We have 22 hospitals. We
24 operate about 100 health care centers and clinics. We
25 have a health plan division with a group of insurance

1 products ranging from the traditional indemnity up
2 through managed care, serving principally the residents
3 of Utah and Idaho.

4 Just a disclaimer, and I begin my presentation.
5 I'm not a professor, I'm not an attorney, I'm not an
6 economist, much of what I say may seem pretty simple,
7 but what I will share with you here today is our
8 perspective as a provider organization on group
9 purchasing, how it works for us and why we're involved
10 in it.

11 I would like to just begin with a statement
12 about the environment that we as hospitals operate in
13 currently. About a year ago, in November 2001, the
14 American Hospital Association released survey data that
15 indicate that as of the year 2000, the end of the year
16 2000, one-third of U.S. community hospitals had negative
17 margins, sixty percent had negative Medicare margins,
18 and nearly two-thirds of U.S. community hospitals lost
19 money on patient care services.

20 So, almost two out of every three community
21 hospitals were relying either on investment income or
22 endowments or some other income stream to make up for
23 losses in their patient care services, or were in the
24 process of going under.

25 In that environment, hospitals are reaching for

1 both the provider and the supplier. The supplier
2 benefits in that their marketing activity and the cost
3 to promote their products to all of the members of the
4 group purchasing organization can be significantly
5 reduced as the group purchasing organization publishes
6 the contracts and promotes the contracts to its
7 membership.

8 The health care provider can benefit by not
9 having to spend time negotiating contracts and being
10 able to divert those scarce human resources to focus on
11 supply chain activity purchasing, receiving, storage,
12 distribution activity, and looking at opportunities in
13 their internal processes to take costs out of the
14 system. If effectively done and with appropriate
15 automation and electronic links, the transaction costs
16 for both parties can be reduced.

17 Almost all U.S. hospitals participate in at
18 least one group purchasing organization. An article in
19 the Wall Street Journal Online just last month estimated
20 that up to 98 percent of hospitals participate in group
21 purchasing associations, in at least one GPO. It's been
22 estimated that up to 75 percent, 50 to 70 percent of all
23 products purchased by hospitals flow through group
24 purchasing organizations.

25 One point that I think is important to remember,

1 because there have been some concern about what market
2 power GPOs may exercise. It's important to remember
3 that hospitals are free to join or not join group
4 purchasing organizations. No one is required to be a
5 part of a group purchasing organization. I'm free to
6 join any group purchasing organization, or to join
7 several group purchasing organizations.

8 The GPOs have to compete for my business, and
9 for hospitals' businesses, and they are free to select
10 GPOs that best represent their interests. Many
11 providers belong to more than one group purchasing
12 organization.

13 Intermountain Health Care belongs to a single
14 GPO, in our case that's Amerinet, approximately 85
15 percent of our nonequipment purchases flow through the
16 group purchase organization. Amerinet offers generally
17 two or more contracts in each supply category, so we're
18 able to choose, again, between more than one supplier
19 for any category of supplies that we're dealing with,
20 again, facilitating choice and competition.

21 We believe in the right of first refusal. We
22 will purchase on GPO contract in every case possible,
23 and every case where a contract supplier has a product
24 that meets our clinical criteria. In the event that
25 there's not a supplier meeting our clinical criteria, we

1 will sit down with the contract suppliers, offer them an
2 opportunity to understand how to meet those, and then
3 only if they're unwilling or unable to meet those
4 criteria then do we look off contract.

5 Our clinicians and our care process models drive
6 the selection process for the products and services and
7 suppliers that we utilize. There are multiple
8 opportunities through surveys, through advisory boards,
9 advisory groups, for us to have input into the suppliers
10 that are selected for contract in our group purchasing
11 organization.

12 In conclusion, we've also found that in a number
13 of cases, group purchase contracts provide a better deal
14 than we can negotiate on our own. A recent example of
15 that was with respiratory products where we participated
16 in an Amerinet/Elite comparative contract process. The
17 resulting contract provides a six percent improvement
18 over the previous best price that we had negotiated as a
19 system.

20 I would just conclude by saying that our
21 experience has been that as we participate in group
22 purchasing, and as we do it appropriately, we're able to
23 reduce costs, we're able to improve the quality to the
24 patients and the communities that we serve.

25 Thank you.

1 (Applause.)

2 MS. DeSANTI: Thank you, Mr. Clark.

3 Next we'll hear from Mr. Manley.

4 MR. MANLEY: Good morning. I've chosen this
5 morning not to use overheads, I thought I would try a
6 low effect presentation. I'm sure we will hear a lot
7 about equipment technology later.

8 Like Bruce, we're a vertically integrated,
9 horizontally managed integrated delivery managed network
10 located in Norfolk, Virginia. We have a full line of
11 products, including a new hospital, short and long-term
12 stay facilities and a lot of products in the insurance
13 marketplace through the managed care.

14 We have developed our environment in an urban
15 area and we do have some advantages there. We are a
16 member of a GPO, and we currently purchase about 30
17 percent of our total spends through thatoTed.

18 I've come today and I thought rather than just
19 talk about Teds in general and our position, I thought I
20 would talk a little bit about whatoI see as trends in
21 the industry, whatoI see as some problems in group
22 purchasing and some areas where we could possibly look
23 for improvement.

24 The industry is changing, I think today the
25 industry has an extreme imbalance. If you look atoit,

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1 those folks that cannot help themselves to manage the
2 cost is a value. So I think they will have a place in
3 the industry, I think that place will be harder to
4 manage as you see more and more of the integrated
5 network technology take place.

6 I think there's some interesting issues out
7 there. One of the issues that we deal with is the cost
8 of change. The question you ask do incumbents have an
9 advantage? Absolutely. Change costs money. It costs a
10 lot of money. It is very difficult to change a thousand
11 bed hospital or a thousand hospitals. I think to that
12 area, sometimes we get stuck with the current
13 manufacturers because their cost in changing those
14 products are not of value to the industry.

15 So, do you ask me if GPOs get manufacturers that
16 they stay with for a long time? Absolutely, and I think
17 there's a reason for that. I think there's a cost
18 reason. That said, does the quality versus cost
19 equation have a place in the industry? Absolutely.
20 Most IDNs, most GPOs, most people use the model I think
21 we use which is ESP which is efficacy, safety and price,
22 it's a three dimensional evaluation. Our IDN will
23 always evaluate quality of product. We will not buy a
24 product just because it is a low-dollar proposal. We
25 will often select products that are not the low-dollar

1 proposal simply because we are meeting a standard of
2 quality to meet our need.

3 I think the policy that GPOs pick low cost items
4 for low quality does not exist because I don't think the
(rcR btryeeyre8y-24oanlep

1 the ability to select products and services, put them in
2 a market basket that meets a need and that need will go
3 forward from there.

4 If there is a bundling concept, I think those
5 bundling relationships will exist directly between
6 manufacturers and new larger IDNs as a partnership
7 function rather than a GPO-driven function.

1 Those of us that can manage our own costs versus those
2 of us that need help in managing our costs. Whether
3 that's a national strategy versus a regional strategy
4 has to be determined. Whether that is a threshold
5 strategy of dollars versus volume, that needs to be
6 determined. But they need to continue to evolve and in
7 my estimation need to evolve a little bit faster to meet

1 MR. BURNS: Thank you. I want to thank David
2 for inviting me down here today to speak.

3 I am going to give you an academic's perspective
4 on group purchasing organizations. I'm not going to go
5 through all of this because some of this has already
6 been covered. But just to summarize a little bit of the
7 different roles that GPOs play in the health care value
8 chain, the roles they perform for their hospital
9 members, and then I think what's more of germane for
10 this audience is to look at the industry structure, GPO
11 revenues and market structure, the concentration of this
12 GPO industry, and see what conclusions we can draw from
13 just a simple industrial organization analysis of the
14 industry as to whether it's competitive or
15 noncompetitive.

16 Finally, just some views of hospitals of the
17 GPOs. You've heard two already. I had the privilege of
18 conducting a four-year field study of not only GPOs, but
19 hospital integrated delivery networks, manufacturers,
20 distributors, e-commerce companies that were trying to
21 disintermediate the supply chain, and in a little bit of
22 shameless self promotion, I have shown you the cover of
23 the book here that was published earlier this spring.
24 But I am from a business school and I actually have
25 brought flyers that offer you a 15 percent discount if

1 you buy it. But that's just the Wharton way of doing
2 things.

3 Basically what the health care value chain is is
4 the following: We have a very complex system. What our
5 field research focused on were the providers, the
6 hospitals which you've been hearing about, the large
7 integrated delivery networks, dealing through a series
8 of intermediaries, whether they're wholesalers on
9 medical/surgical and drug side, or group purchasing
10 organizations purchasing products on their behalf
11 dealing with the whole series of product manufacturers.

12 What our book dealt with was this whole right
13 side of the equation. I think it's helpful to just to
14 have this picture in mind, because you need to view the
15 GPOs in context and what they are is essentially an
16 intermediary. As an intermediary, they are subject to a
17 lot of market pressures, because in a number of
18 industries, there are trends towards disintermediation,
19 or cutting out the middle man.

20 We see that right now with a number of the large
21 integrated delivery networks trying to act either as
22 their own GPO or their own wholesaler or in sometimes
23 both. So the GPOs are quite cognizant of this, and
24 they're facing a number of market pressures from their
25 own hospital members over here who are trying to

1 hospitals may join.

2 So, it's a huge important difference to
3 understand. There are also membership differences,
4 whether or not they represent hospitals, there's the
5 physician or alternate site markets, geographic
6 differences. They're subject to antitrust limits on how
7 big they can be. And often times it's hard to
8 distinguish the GPOs from the integrated delivery
9 networks that you've been hearing about.

10 Intermountain Health Care is one of the three
11 largest shareholders of Amerinet, and so to some extent
12 they're indistinguishable.

13 This is a slide from our book in terms of
14 looking at the GPO revenues and market share. You can
15 see why the attention in the New York Times article was
16 so heavily focused on Novation and Premier is because
17 they have a whopping share of the hospital market.
18 These are the big five on the nonprofit side and the big
19 two on the for-profit side.

20 Now, it's interesting, if you look at how
21 concentrated the GPO industry is, you can do it one of
22 two ways: First you can do it as a percentage of the
23 medical supply and pharmaceutical spending that GPOs
24 actually penetrate. And going back to my prior slide,
25 we're looking at this \$47.7 billion that GPOs actually

1 penetrate. The top four GPOs, they constitute \$36
2 billion of that or almost 76 percent of the GPO
3 penetrated spend is accounted for by four top GPOs, with
4 a very high concentration level.

5 However, if you look at the concentration of the
6 GPO industry in terms of the total amount that hospitals
7 spend on their medical and pharmaceutical supplies, you
8 will see that the picture is quite different. The total
9 supply is estimated to be roughly \$67 billion, and like
10 a true academic, I have, you know, an upper and lower
11 bound estimates here, and a footnote, the top four GPOs
12 account for \$36 billion of that, which is only 54
13 percent accounted for by the top four GPOs, with a
14 concentration level which is roughly half of what you
15 see in the top panel.

16 So the numbers you use to look at the
17 concentration of this industry are extremely important.
18 Why the big difference between the upper and lower
19 panel? Well, a number of the reasons have already been
20 mentioned. First, hospitals can direct contract with
21 manufacturers for their supplies and totally circumvent
22 their own GPO.

23 Secondly, the GPOs actually only account for a
24 percentage of all the medical supplies and
25 pharmaceuticals that hospitals buy. It varies by the

1 type of product. Of that percentage, hospitals only
2 comply with the contracts a percentage of the time. So
3 what the GPOs are actually intermediating is a
4 percentage of a percentage, and that's why the lower
5 panel on the prior side is so much different than the
6 upper panel, because the GPOs only contract for a
7 percentage of a percentage.

8 There's also, as JoAnne mentioned, extreme
9 variation among the GPOs in how well they monitor these
10 contracts. In addition, as has been mentioned,
11 hospitals belong to multiple GPOs, with multiple GPO
12 memberships, you have divided loyalties and hospitals
13 can shift membership share from one GPO to another,
14 although that has not yet been documented how
15 extensively or quickly that takes place.

16 As we can see, hospitals can purchase directly
17 through their own integrated delivery networks and act
18 as their own GPO. Finally, hospitals will act
19 independently of their GPO, even when they're
20 shareholders of the GPO when it's in their own self
21 interest to do so.

22 So, in my view, the GPOs really have a challenge
23 in trying to control their hospital members who have
24 voluntarily joined them and I think the biggest
25 challenge they have is just acting as a coherent body.

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1 Mr. Goodman?

2 MR. GOODMAN: Thank you very much to the FTC and
3 to David in particular for having me here.

4 The Lewin Group was commissioned by the Health
5 Industry Purchasing Association to conduct a study, a
6 survey study of the clinical review process conducted by
7 group purchasing organizations and health systems. I'll
8 tell you a little bit about it.

9 Here's a summary of our approach: It involved
10 surveying five major health systems and six GPOs earlier
11 this year. We interviewed a set of purchasing managers,
12 administrative officers and medical officers of the
13 health systems, upper-level executives, clinical
14 operations directors of GPOs, conducted the interviews
15 primarily by telephone using a detailed interview guide
16 that was sent to all participants prior to the calls.

17 We developed this interview guide with input and
18 comments by HIGPA, and left out of the study were
19 proprietary aspects. We did not ask about contract
20 terms, financial arrangements and business tactics, we
21 were primarily concerned about the clinical review
22 process.

23 Here are the GPOs that we surveyed. You can
24 tell from the previous presenter that these GPOs account
25 for a significant portion of the market. Here they are.

1 And I wanted to get just go right into our main
2 findings.

3 Now, the most interesting thing I found in doing
4 this study was really the breadth of technology
5 attributes and impacts that are incorporated into
6 clinical review processes. What one might expect
7 typically is you'll see right in the middle there,
8 economic attributes, because we think that GPOs are
9 largely about price, but when quizzed on this, the
10 people that run hospitals and make these decisions and
11 the GPOs themselves tell us the kinds of factors that
12 you've got to bring to bear to make decisions about
13 these kinds of technologies.

14 I think Dr. Hammer referred to them as nonprice
15 concerns. Nonprice concerns are quite present and
16 prominent in these decision processes. Look down the
17 list, technical properties and performance: Does the
18 thing work or not, you know, when you plug it in.
19 Safety to patients and health care workers, efficacy and
20 effectiveness, economic attributes themselves are not
21 confined to price.

22 Cost, cost effectiveness, cost utility, cost
23 benefit, charges, ability to be reimbursed by a variety
24 of third party payers. Those fall under economic
25 attributes alone. Acceptability to patients and

1 clinicians, you know, ergonomic concerns, risk of
2 liability, potential for standardization.

3 We're not done. Impact on market share and
4 competitiveness, work flow considerations, reputation
5 support provided by the manufacturer, and this one came
6 up a lot, capacity of a vendor to provide sufficient and
7 reliable supply. If you look at just what the price is,
8 you're only getting a small bit of the story.

9 One of the challenges that the hospitals and
10 GPOs face is to how to incorporate and weigh and
11 interpret these various factors in making these
12 decisions.

13 Our first main finding, though, is the clinical
14 review processes of health systems, GPOs rely upon
15 comprehensive systems of expert committees. It's not a
16 one-person decision-making operation, and one of the
17 interesting things that I found in particular, because I
18 deal with technology assessment efforts around the
19 United States and the world, is increasing multinational
20 interdisciplinary processes in bringing together the
21 right set of experts to weigh in on all of these issues.
22 This is really held in common by the groups that we
23 talked to.

24 They also, interestingly enough, used some of
25 the same recognized independent technology assessment

1 resources. I know that groups, hospitals and other
2 purchasers, providers, payers, use ECRI and Hayes and
3 other technology assessment vendors. They use Medline
4 and other databases, and lo and behold those are the
5 kinds of things that we found.

6 As a matter of fact, I think it's a consortia
7 that provides access to the Hayes technology assessments
8 to all of its member institutions to help not only those
9 member institutions but to help the consortia itself in
10 weighing these decisions.

11 The health systems and GPOs have functions for
12 monitoring and incorporating what we sometimes call
13 break-through and other novel technologies. One of the
14 great challenges here, I must say, is the great wealth,
15 or I should say the width of the new technology
16 pipeline. There's a lot of bandwidth of new technology
17 here, and part of the issue is trying to identify these
18 truly novel and break-through technologies and trying to
19 keep track of these and the various ways in which GPOs
20 and the large hospital systems try to track these
21 things.

22 These functions include the capacity to respond
23 to initiatives from the technology companies and vendors
24 themselves as well as actively seeking out, that is
25 horizon scanning for new technologies.

1 But of course consideration of such technologies
2 is still subject to the same bits of demonstrating
3 safety, effectiveness, cost effectiveness, reliability of

1 systems.

2 One of the most interesting ones that I came
3 across was one GPO has a clinical technology service.
4 They're kind of the guys in the garage if you will
5 looking under the hood that undertake repair,
6 maintenance and upgrade from any types of capital
7 equipment. They have a communication capability with
8 other aspects of the clinical review process in that
9 organization.

10 To exchange information about how well do these
11 things work in practice, what kind of feedback are we
12 getting? Are there any kinds of problems? This
13 feedback group is important.

14 I'll break to the sixth. GPOs interestingly
15 enough can facilitate trials. I think there's more
16 potential here for this than has been realized to date.
17 But the fact that you've got organizations dealing with
18 many, many hospitals across many different product
19 lines, and many suppliers, they're obviously interested
20 in the marketplace among the innovators, the purchasers,
21 the clinicians, patients, payers even, to get rolling
22 clinical data about the effectiveness of these
23 technologies in the field.

24 In that sense, and to a small sense thus far,
25 GPOs are in a position to facilitate clinical trials.

1 Interesting.

2 Now, just some quotations that I think help
3 summarize some of the observations. There truly is an
4 inclination towards evidence-based evaluations. This is
5 not, you know, just a story by GPOs and health systems,
6 throughout health care decision making. There is an
7 inclination towards evidence-based policy,
8 evidence-based decision making that draws upon some of
9 the same technology assessment outfits and the same
10 information sources as everyone else out there.

11 As one of our interviewees said, the GPOs are
12 not locking out newer cusp technologies. They evaluate
13 products on the merits, they do trade-offs of cost and
14 effectiveness and use best evidence.

15 So, this is not unique to GPOs and health
16 systems, but it's important to point out that in our
17 observation, GPOs and health systems are part of this
18 wave of evidence-based decision making.

19 Much of the clinical review activity is devoted
20 to technologies that are recently FDA approved or whose
21 approval is imminent. One fellow said that mostly we
22 see the break-through products of these clinical review
23 processes and he mentioned pulse oximetry as originally
24 looked at as a kind of commodity, but if there's a new
25 feature in a device like that that makes it not just a

1 commodity or not just a me-too product, but potentially
2 a break-through, these are the kinds of things that
3 should come to the attention to the clinical review
4 processes.

5 Every single case that hits these clinical
6 review processes, with this GPO in particular, it
7 involves an extensive financial analysis. They used to
8 not be so rigorous about this, but they're getting more
9 rigorous, as are other decision makers in the field.
10 So, these require a focus in how they change care, pair

1 that HIGPA has copies of our study as well.

2 With that I will close.

3 (Applause.)

4 MS. DeSANTI: Professor Latham?

5 MR. LATHAM: The panelists yesterday stayed
6 seated at the panel and I thought that getting to sit
7 might be a reward for not bringing PowerPoint. So, I'll
8 try and collect on that.

9 From the panelists you've seen so far, you might
10 not be aware that there's actually a lot of controversy
11 about GPOs. Everyone so far has been very optimistic
12 about the value of GPOs and what they add to the quality
13 chain and so on. It's my unfortunate duty to inject a
14 little bit of the dark side, but I do it from my point
15 of view as an independent, nonconsulting law professor
16 with special attention to the existing guidelines.

17 I know, by the way, that they aren't
18 "Guidelines," but when I say the word "Guidelines," I
19 just ask you all to imagine or pretend that I said
20 "Statement of Department of Justice and Federal Trade
21 Commission Enforcement Policy." I'm talking about
22 specifically number 7 of those, the one that deals with
23 joint purchasing arrangements.

24 That statement is -- well, it was being
25 developed about a decade ago, and it's actually quite

1 optimistic about joint purchasing arrangements. It
2 begins with a sweeping statement, "Most joint purchasing
3 arrangements among hospitals or other health care
4 providers do not raise antitrust concerns." It repeats
5 things like this throughout, and its structured in a
6 way, it doesn't carve out safe harbors, it basically
7 announces that the sea is safe, and it carves out two
8 sort of danger harbors, if you like.

9 The two danger harbors are these: First, the
10 enforcement agencies say that they will be concerned if
11 GPO purchases account for more than 35 percent -- if a
12 given GPO's purchases account for more than 35 percent
13 of total sales in a relevant market. Here they're
14 talking about sales from product vendors through the GPO
15 to the hospitals.

16 The concern there basically is with monopsony
17 power. Are GPOs large enough to have monopsony power to
18 be able to drive down the prices of the goods they're
19 purchasing on behalf of their hospital members to
20 subcompetitive levels? If they are, the concern with
21 that would be that we might see some reduction in
22 production of those products, because of the
23 subcompetitive returns, we might also see reduction in
24 quality of those products as the vendors try to sell
25 products at subcompetitive prices.

1 There's a fixed number -- roughly -- of tongue
2 depressors and needles that the world needs and it may
3 be that the vendors depress quality if they can't reduce
4 numbers of output. The other concern that the existing
5 statement has is the possibility that competitors in the
6 same market will purchase so much of their -- well, it
7 refers to 20 percent, an amount equal to 20 percent of
8 their revenues -- purchase so much product through the
9 GPOs that that common purchasing between competitors
10 will have a tendency to stabilize competitors' price
11 structures in a way that will facilitate price fixing.
12 Or perhaps even that GPOs will communicate between
13 competitors in the course of purchasing so much of the
14 competitors' supplies that that will give rise to
15 anticompetitive price fixing.

16 So, there are basically two unsafe harbors in
17 the otherwise pleasant sea of group purchasing on the
18 model in statement 7, and these are the possibility of
19 monopsony power and the possibility of stabilization of
20 cost structure across competitors.

21 Now let me turn to what some of the allegations
22 are now that you might have read about in the New York
23 Times about anticompetitive GPO affects, and I want to
24 see how well they fit with the existing concerns in
25 statement 7. And I want to be agnostic. I'm delivering

1 out of given hospitals to confine market share.

2 In addition to this, there are related
 3 allegations that although, for example, hospitals can
 4 belong to multiple GPOs, the GPOs may have contractual
 5 provisions tied and enforced to these rebates that say
 6 that you can't purchase goods from a different GPO if
 7 our GPO offers a good in that class, or say that you
 8 can't purchase goods from outside the GPO without losing
 9 rebates across multiple products or multiple years if we
 10 offer a good in this class.

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1 exclusionary contract practices.

2 How does this set of allegations, whether true
3 or not, fit with the concerns of the existing statement
4 7? And the answer is they don't fit at all. Because
5 none of these allegations are predicated on the idea
6 that there is market power causing subcompetitive
7 pricing, and none of these are based on the idea of cost
8 standardization among competitors.

 So, the existing guidelines really have not Slrwd (,mpet

1 What kinds of contract provisions really are out
2 there? Are these allegations about tying discounts to
3 bundled goods and tying them over years, are these
4 false? Are they true? What kinds of competitive
5 justifications are there for the contractual provisions
6 that are out there? What kinds of possible
7 anticompetitive effects might provisions have in the
8 alleged provisions are out there? Are there exclusivity
9 provisions? Are there adequate provisions about
10 disclosure?

11 One interesting feature about the whole GPO
12 market as we heard from the GAO earlier is that these
13 are purchasing agents for hospitals, but they're funded
14 by administrative fees from the device makers. They're
15 not -- in other words, there's a principal/agent
16 relationship, but the agent is not being paid by the
17 principal here. We need to see whether such
18 exclusionary provisions as there might be make adequate
19 reference to the principal/agent relationship and also
20 fit well with competitive concerns.

21 Are there limits to economies of scale here?

22 One way of interpreting the GAO data is that -- and the
23 idea that larger groups break free from joint purchasing
or group purchasing organizations is that at so0 TD (23) Tj 53.2

1 to a certain size, and yet we see a couple of the larger

1 were representing nonprofit hospitals and everything is
2 hunky-dorey. Even in the hearings themselves, we heard
3 quite a bit about the good nature of the GPOs and how
4 they're here to save the world. Now we're starting to
5 see the GPOs come around the corner and agree that they
6 have been involved in some contracting practices that
7 are harming industry and harming patient care, and we're
8 seeing that through the codes of conduct that they're
9 now starting to develop in both Premier and Novation,
10 the primary players here that I'll talk about today have
11 put forward codes of conduct of how they're going to do
12 business in the future that will create a better
13 environment.

14 As a note to those codes of conduct, HIGPA also
15 has a code of conduct more of an industry-wide. They're
16 a good start, but we've got a long way to go with those.

17 The bottom line is what you have in the
18 contracting processes, and again, I'm going to speak
19 today more specifically what is happening to companies
20 that I know about in the marketplace. You have sole
21 sourcing agreements, 95 percent compliance. Some of
22 them are 100 percent compliance. You have bundling of
23 products that are unrelated.

24 I'll just give you an example here. The
25 spectrum opportunity program at Novation bundles

1 adhesive drapes, tapes, dressings, sterility products,
2 blades, sutures, gloves, these are all bundled together
3 into one contract, and I'll point out how that can
4 actually have a detrimental effects in a moment.

5 Exclusionary pricing has already been mentioned.
6 Rather than the volume of products that you buy will,
7 you know, get you a better price, it's done on
8 percentage. As long as you stay within a compliance
9 percentage within that contracting group, then you get
10 your bonus, you get your check at the end of the month,
11 but it's not on how much you buy.

12 Vendor fees, GPOs have talked about their vendor
13 fees being below the three percent ratio. That's true
14 only to the extent that if you only count administrative
15 fees, what they consider administrative fees, and if you
16 look into the fee structure that's going from vendors to
17 the GPOs far exceeds three percent in many times.

18 And the price controls. We have companies that
19 have actually gotten contracts with the GPOs and they
20 have been told to basically increase their prices making
21 them less marketable to within the structure of the
22 agreement.

23 I'm going to detail a couple of companies and
24 I'm going to kind of go fast here, because we've got
25 several that I want to talk about. Masimo is somewhat

1 of a poster child from the Senate hearings and also from
2 our association, but you had a company that had 50
3 independent studies. We heard earlier today about the
4 effective use and these clinical groups that are going
5 to evaluate products.

6 Masimo is a company that had a new product, they
7 had 50 independent -- independent, not paid-for-by-
8 Masimo studies -- saying that their product was
9 superior. They actually had, I will show you a slide in
10 a minute, they had a lower price than the incumbent
11 vendor, and they failed to get on contract.

12 So, at some point within this framework, you
13 have to start asking yourself if we have clinical groups
14 and we have pricing and other issues to look at as far
15 as how do you evaluate a product. If you have the
16 superior product and you have a superior price and you
17 can't get on contract, that begs a few questions.

18 Bundling is really where we're seeing the major
19 problem here. I mentioned some of these products before
20 that are bundled together. In Masimo's example, if a
21 hospital purchases a Masimo product, it not only loses
22 their structure within the spectrum opportunity or their
23 pricing structure, they may have to repay savings from
24 previous years up to five previous years back to the
25 GPO.

1 So, you have a structure that's not only a
2 bundle, but there's a penalty for changing products that
3 can actually travel years back. In Masimo's case, I
4 think at the end of the day you have to look at pricing,
5 which is the GPO's role is to save money, bring the best
6 products at the best price to the market. That market
7 should be free and open. It should be an open
8 marketplace. If you have a marketplace where with
9 non-GPO hospitals you win almost every time, you have
10 the superior product at the best price, but within the
11 GPO realm, you can't seem to get a contract, and your
12 competitor is more expensive, again, I think it begs
13 questions.

14 This is a specific example. Masimo had a bid,
15 they were the lowest price. They have 50 independent
16 studies, including the Internal Clinician Group thought
17 Masimo's product was better, and what happened was, Tyco
18 Nellcor offered to give basically a rebate on sensors
19 back to Novation for every time the hospital bought a
20 sensor. Meaning about \$6 million per year back to
21 Novation. So, Tyco got the contract.

22 Again, I have gone through some of these things.
23 In this particular product, you have 12 unrelated
24 products bundled. Ninety-five percent compliance rate.
25 I will caveat that only with Ethicon's endomechanical

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1 Over the last ten years, I don't know if it was
2 100, I haven't been in this field for ten years, but you
3 had a multitude of Trocar manufacturers. Today you have
4 ten. In Masimo's example, I believe there were over 20
5 oximeter makers in the United States ten years ago.
6 Today there are two or three.

7 So, what you are seeing is exactly what some of
8 the professors and the analytical minds are talking
9 about, is there market pressure from their contracting
10 practice that are changing the market? Without
11 question.

12 Retractable Technologies, I'm going to go
13 through fairly quickly. Retractable Technologies makes
14 a safety needle. They had a hard time getting onto
15 contract again, got on the contract through a
16 subcontractor, not on the bundle, not able to get
17 market share beyond a certain percentage. And that
18 is a perfect example.

19 Baptist Health Systems, San Antonio, if they buy
20 even one box of Retractable Technologies products, they
21 will lose \$300,000 in rebates. So, is it voluntary to
22 join a GPO? Is it voluntary to join the Spectrum
23 program? Yes and no. If you need sutures, J&J, they
24 control over 90 percent of the marketplace. If you need
25 syringes, Beckton Dickinson controls over 90 percent of

1 the marketplace. That's the Spectrum bundle.

2 So, if you're a hospital and you need any
3 average commodity product, you are probably going to get
4 into a Spectrum bundle. The price you are going to pay
5 is any price down the line and you are going to have to
6 stay within that compliance ratio or you are going to
7 have to repay the money saved.

8 Utah Medical, I am going to go fairly quickly
9 because I am running out of time. Utah Medical provides
10 a device that you put in the uterus during pregnancy and
11 during birth that measures the pressure of the womb.
12 They were the first company in the marketplace, they had
13 a superior product. Premier did not believe that they
14 were a big enough company to actually contract with
15 them. They wanted to go with a Tyco subsidiary because
16 they could bundle other Tyco products.

17 Premier contracted with Tyco in '97, without
18 bidding, and you can see what happened to Utah
19 Medical's -- Utah Medical was the leader in the
20 marketplace. They had the number one device. You can
21 see what happened to their marketplace after Premier set
22 up a '97 bid without contract or contract without
23 bidding.

24 I think what I am hoping that you pull from my
25 part of the presentation is that we can talk about the

1 general sense of the law and we can talk about the
2 general sense in the spirit of what happened in '97,
3 but what we need to look at is the marketplace and who's
4 being affected by this. Eventually it's the patients
5 who are affected. Again, I think some of these
6 anticompetitive effects we've already discussed. At the
7 end of the day, what you have to look at, there are
8 fewer companies coming out with new products, fewer
9 innovations, and the companies right now, the ability of
10 a company to start out, create a device, and go to the
11 marketplace is severely hampered by GPOs' long-term,
12 sometimes seven-year contracts with primarily the top 20
13 manufacturers of medical devices in this country.

14 And two more slides here. Basically, again,
15 they have become gatekeepers for access to these
16 hospitals. The bottom line is, at the end of the day,
17 if you have Tyco, Beckton Dickinson, J&J who control
18 over 90 percent of these markets and they are bundled
19 together with other products, then it makes it very
20 difficult for companies to get into this marketplace.

21 I will just leave this up here for a second. If
22 anyone wants a copy of this presentation, they can
23 contact any of these folks.

24 (Applause.)

25 MS. DeSANTI: Mr. Betz?

1 MR. BETZ: As the last speaker on today's panel,
2 I feel a little bit like my old friend Bob Merkle, right
3 before he went up for his fifth wedding. I asked him
4 how he felt, he paused and looked at me and he said,
5 "Robert, he said I know what's expected of me, I just
6 don't know how to make it new."

7 But I would like to visit with you today, we
8 will cover some of the points that my esteemed panel has
9 made.

10 That was a picture of my grandfather.

11 What I would like to visit with you about is
12 briefly talk with you about an overview of our industry,
13 the savings that we contribute to health care
14 organizations today. I want to mention the code of
15 conduct our industry has developed, I would like to
16 touch briefly and follow up Ms. Bailey's comments about
17 our views on the GAO report and then talk with you about
18 what we are doing to add to the body of knowledge
19 through an industry assessment.

20 We are the purchase agents for the buying
21 cooperatives for hospitals and other health care
22 providers. Most group purchasing organizations in this
23 country are owned by hospitals, all are ultimately
24 responsible to hospitals. The FTC, I believe, was
25 created in 1914, four years before that, the first group

1 purchasing organization was established in New York
2 City.

3 What do we do? We aggregate buying power to
4 negotiate discounts, we survey the marketplace for
5 clinically desirable products, we negotiate and
6 administer contracts on behalf of hospitals, we lower
7 hospitals' operating costs, we streamline the purchasing
8 process, and we promote safety and quality of care.

9 Seller-based fees and buying cooperatives are
10 widely accepted competitive business models in many
11 industries. I would call to your attention they exist
12 in agriculture, real estate, insurance, and are used
13 extensively by the United States Government.

14 Groups typically return fees in excess of
15 expenses to the hospital members. In 1986, Congress
16 sanctioned the GPO model for health care programs by
17 exempting supplier-paid administrative fees from
18 Medicare and Medicaid antikickback statutes. In 1991,
19 adding to the statutory exemption, the safe harbor
20 regulation requiring disclosure to members of the vendor
21 fees paid to GPOs was added, but it allows competition
22 to determine the level of those fees.

23 Let me talk with you about -- you heard, I
24 believe, yesterday, from the American Hospital
25 Association and from some of the earlier speakers about

1 expenditures in one year by \$886 million, increase
2 spending by state and local governments by at least \$249
3 million. A one percentage point decline in the rate of
4 GPO savings would increase Medicare and Medicaid
5 spending by \$1 billion annually. Veterans Affairs would
6 face an additional calendar year expenditure of at least
7 \$61 million.

8 Our code of conduct. There have been recent
9 concerns expressed regarding the business relationships
10 between group purchasing organizations and vendors that
11 pointed out the need for us to tell a better story, to
12 reassure the public that the industry does and will
13 continue to practice the highest ethical standards.

14 Our code focused on several areas. And again,
15 this is included in your written materials. Eliminating
16 the appearance of conflicts of interest, ensuring open
17 communication between members and vendors, establishing
18 guidelines for the use of contracting tools. In
19 addition, reinforcing full disclosure to members of all
20 vendor payments that are received, establishing a
21 reporting and education programs, including surveys,
22 that quantify the value of a group purchasing
23 organizations, and then finally demonstrating the value
24 of our cost savings.

25 Our code of conduct is a baseline for the

1 industry. We believe it is a historic document, the
2 first time that the health care supply chain has ever
3 come together in such a fashion. It is now in the
4 implementation phase. We are looking for a full rollout
5 in January.

6 Individual group purchasing organizations are
7 moving ahead adding their own principles to the GPO
8 baseline business practices.

9 I want to say a word just about our friends over
10 at the General Accounting Office. GAO is conducting a
11 new study of the industry. I think Ms. Bailey's
12 comments earlier today about their first study being
13 limited is indeed correct. They were under a difficult
14 timeline and under difficult circumstances in doing
15 this. We are looking forward to working with the GAO as
16 they conduct a more comprehensive study.

17 This study, I believe, we're contributing
18 information and working with the GAO staff hopefully in

1 also the Lewin Group, as mentioned by Cliff Goodman
2 earlier. HIGPA has commissioned a study that has
3 concluded that GPOs facilitate significant expert
4 clinical input into group purchasing decisions. Again,
5 that study is available to you as well.

6 This is my forecast: I believe that groups are
7 going to continue to attract interest from many sectors
8 in the government, but we believe that the end game will
9 be a re-affirming of our fundamental value that we
10 provide which we believe are the best products at the
11 best price for the patients that we ultimately serve.

12 In closing, I just would call your attention, I
13 don't know how many of you are readers of U.S. News and
14 World Report, they come out every year with a listing of
15 the 100 best hospitals in the country. If you get an
16 opportunity to look at it some time, I would urge you
17 to. I know that I find it interesting that everyone of
18 those 100 hospitals belongs to and is an active
19 participant in a group purchasing organization.

20 Thank you all very much.

21 (Applause.)

22 MS. DeSANTI: Thank you all. We've covered a
23 lot of ground here, and we're going to try to have some
24 discussion. I think first we would like to take a step
25 back and take a broader look at the issues.

1 Matthew, do you want to start?

2 MR. BYE: We've been mainly discussing short-run
3 implications here and I would like to switch to the long
4 run. What I am interested in hearing about is market
5 structure innovation and the effect that GPOs may have
6 on these.

7 MS. DeSANTI: When you want to respond, could
8 you just turn your name tent up on end like that. Okay,
9 another demonstration, I'll do it again.

10 Yes, Cliff?

11 MR. GOODMAN: Yes, an important question. Are
12 GPOs in the long run a factor in technological
13 innovation? Yes. However, before we leap to GPOs,
14 let's look to other factors that I think in my opinion
15 have a greater influence on innovation today and in the
16 future. That is the technology market is a very tough
17 one, and it needs to be.

18 Before we even consider the role of GPOs, it's
19 tough enough to get proof of concept. It's tough enough
20 if you're a device, drug or biotech, to get approval
21 from the world's toughest regulation agency, the Food &
22 Drug Administration. It's tough enough if you've made
23 it that far to show that you're going to get third party
24 payment from the world's largest third party payer,
25 Medicare. Aside from not tens, not hundreds, but

1 very smart about this. It used to be the VCs -- the VCs
2 follow the same model I recently just did. You aren't
3 going to get upfront support without some promise of
4 proof of concept. Then they start saying, well, how do
5 you look for FDA approval, what's your glide path for
6 that? The smart ones over the past several years are
7 saying great, FDA approval, can you show me that there's
8 going to be a payer market out there for you? And yes,
9 the GPO issue is coming up, but I see it as coming
10 subsequent to these other larger hurdles.

11 MS. DeSANTI: Professor Burns?

12 MR. BURNS: Yeah, a different set of issues with
13 regard to market structure. It's my impression from
14 having studied the GPOs over the last few years that the
15 largest GPOs have actually reached the antitrust limits
16 in terms of how big they can be, in terms of the number
17 of hospitals. If you look at Novation and Premier,
18 they're not really adding more members these days,
19 they've pretty much hit the 30, 35 percent cap that was
20 stated in the FTC and Department of Justice guidelines.
21 They're actually looking to grow in other ways.

22 So if you're to look down road, long-term, in
23 terms of the market structure, they wouldn't necessarily
24 change in terms of the number of hospitals that belong
25 to them, what they would like to do is increase the

1 So, from a purely market structure point of
2 view, this is a fairly competitive industry. Now, some
3 of the other, you know, issues raised here deal with
4 things other than strict market structure.

5 MS. DeSANTI: And let me ask you, just as long
6 as I have you, from your research, are you at all aware
7 of the extent to which bundling and other exclusionary
8 types of contracts are prevalent among GPOs these days?

9 MR. BURNS: Yes, we actually studied bundling
10 from a number of different perspectives. Not only the
11 GPOs' perspective, but also the manufacturers who are
12 trying to bundle these products and use them, as well as
13 from the hospitals and purchasing bundles. Bundling is
14 not a clear-cut issue. The manufacturers would love
15 nothing better than to bundle products and get hospitals
16 to buy them.

17 However, when those bundled packages include
18 items that are high in clinical preferences, and you
19 have a number of different physicians on staff who have
20 different preferences, product bundling breaks down.
21 This happens at the micro level in the hospital, at the clinical
22 floor, when multiple physicians have different
23 preferences and you can't get one bundled package to
24 suit them.

25 So, bundling is one of those things that GPOs

1 and manufacturers would like to do, but here again it's
2 resisted at the micro level when clinicians are ordering
3 and using these products. I'm not convinced that that's
4 a good long-term strategy either, and I think you have
5 heard some of the other panelists say here, that's a
6 road that's been already traveled and they are going to
7 look elsewhere.

8 MS. DeSANTI: Mr. Clark?

9 MR. CLARK: I would like to just reinforce what
10 Lawton just said regarding the introduction of new
11 manufacturers and technology into our system. Our
12 experience is a bottom-up process, and no GPO,
13 unfortunately no hospital administrator can control
14 who's visiting with our physicians about which product
15 or which technology.

16 Those things continually get exposure, and many
17 of the contracts that we currently operate under in our
18 group purchasing organization result from strongly
19 expressed clinical preference working its way up through
20 our process. We don't have GPO bundled agreements that
21 drive anything. We're not penalized in terms of fees or
anything for what we might purchase either on or off2rm-uwher. te

1 those are determined by our clinical staff at the micro
2 level, as was set, and that works its way up, and that
3 determines what we purchase.

4 I might add that, you know, Masimo was
5 mentioned. Our group purchasing organization was the
6 first, I believe, to contract with Masimo, and we have
7 an active process of looking at new technology in our
8 system and through our GPO.

9 MS. DeSANTI: Professor Latham?

10 MR. LATHAM: I feel like Orson Bean here. I
11 would like to take your question and use it to -- of
12 course I would -- to reinforce what I said earlier.

13 MS. DeSANTI: Of course.

14 MR. LATHAM: Which Commissioner Riley gave a
15 speech in which she talked about the FTC's turning to
16 address short-term versus long-term considerations,
17 questions about short-term pricing benefits to be
18 balanced against questions of longer term benefits from
19 innovation.

20 We've heard a lot today about the plight of
21 hospitals and what the good things that GPOs do for
22 hospitals that are in this difficult financial
23 situation, and that might be in tension with questions
24 about the effects of innovation on the hospitals but
25 more importantly on their patients long into the future.

1 So, again, rather than trying to answer the
2 concrete question about whether there's that tension
3 right now, I do get the sense sitting here that, you
4 know, we live in the post-modern world where the number
5 of different market shares for GPOs that have been
6 announced by various members of the panel were just
7 wild.

8 So, I am not qualified to have an opinion on
9 which of these things is true, but I do urge the FTC to
10 start thinking about whether the guidelines in this area
11 are taking account. For example, there's nothing in the
12 statement on group purchasing that has anything to do
13 with injuries to innovation over the long-term. The
14 statement is designed only to address short-term price
15 equilibrium types of problems. The economics world has
16 moved past that and the GPO world has moved past it in
17 terms of industry concentration in GPOs and industry
18 concentration in device manufacturer.

19 So, back to you.

20 MS. DeSANTI: Thank you.

21 Mr. Holden?

22 MR. HOLDEN: Short-term/long-term, I think
23 without question as Ves Weatherman [phonetic] said
24 during the hearing, there is an impact to the venture
25 capital community providing funds for young companies if

1 they believe that they're not going to get through the
2 GPO. The FDA, I think it's a telling statement that one
3 of the most burdensome federal agencies, the FDA, is
4 just one of the factors along with GPOs that venture
5 capitalists look at to determine whether they're going
6 to fund a company.

7 So, I think that's a telling statement. The
8 issue down from the other end of the table, are all GPOs
9 bad? No. Are even Premier and Novation, you know, do
10 they provide a value? I think they do. The question
11 becomes, is that standardization? If it's across the
12 country, is that going to harm innovation and is that
13 going to in the long-term bring about market effects

1 were already here in what Lawton said. I think
2 technology is alive and well especially in the
3 innovation marketplace, because technology is a patient/
4 physician process. And only patients and physicians
5 work with that process.

6 It's difficult to manage across six hospitals
7 and get a technology standardization to believe that a
8 GPO is going to be able to sell stents from Dallas and
9 convince somebody in Norfolk that that is the product to
10 buy just doesn't exist. Technology today is a
11 relationship that's basically a peer pressure between
12 physicians and the skilled sets, of course, of the idea
13 is to be able to develop a mechanism to work with the
14 physicians and standardize them. But the technology as
15 a GPO given the knowledge that is standard in this
16 industry today.

17 MS. DeSANTI: Thank you.

18 Professor Latham, we take your points about the
19 guidelines. I think it's certainly true, and I'll add
20 this just so the audience has the benefit of some
21 thinking from the FTC. The guidelines were developed in
22 1993. The first time that innovation theories and
23 theories about innovation and competition showed up in
24 other guidelines was in 1995 with the intellectual
25 property guidelines.

1 These are theories that the agency has been
2 developing over the past several years. Certainly no
3 investigation in any area is necessarily constrained by
4 existing guidelines in terms of if there are further
5 developments. Those will always be assessed.
6 Exclusionary stories are ones that have been difficult
7 to articulate in guidelines because of conceptual
8 differences and different types of fact patterns, but
9 certainly they do exist in antitrust.

10 If you look at some of our cases, they are ones
11 that are used from time to time, and guidelines are very
12 costly effort for the agencies, but it's certainly true,
13 and you're making a fair point, that the anticompetitive
14 stories that are currently covered by statement 7 don't
15 include the types of stories that we're hearing about
16 today, and that's a very important point. I just wanted
17 to add the other points about how the agencies tend to
18 approach things.

19 I would like to ask one other basic point and
20 maybe, Mr. Betz, you could respond and I'm sure others
21 will have insights into this as well: I'm wondering
22 about how the basic structure that presumes that
23 administrative fees are coming from the vendors rather
24 than from the hospitals, how that was determined. It's
25 certainly true, the point that you made in your

1 presentation was that seller-based fees are a common
2 phenomenon, and that's certainly true. They can also be
3 controversial, and since I'm working on a study on
4 slotting allowances now, I can tell you that in the
5 retail industry, they are sometimes controversial, and
6 they raise the same kinds of issues in terms of possible
7 exclusion stories.

8 I'm just wondering, if it's the case that
9 administrative fees are basically based on fees from the
10 vendors, presumably they are giving you discounts
11 through those fees, in essence they can give you a
12 discount or they can pay you a fee. Why is the model
13 that you get fees from the vendors rather than simply
14 getting the largest discount that the vendor would give
15 you and then relying on the hospitals to take some
16 portion of that fee to pay the administrative cost of
17 the GPO? What are the advantages of a seller-based fee
18 model?

19 MR. BETZ: First of all, seller-based fees
20 exist, as I mentioned in my comment, in other
21 industries. And I would again emphasize that it is
22 utilized by the federal government, the Department of
23 Defense, the Veterans Administration, what's the other
24 one? General Services Administration. I would say to
25 you that these fees -- first of all, group purchasing

1 organizations historically back 32 years ago when I
 2 first got into health care, group purchasing
 3 organizations were of two types: Those that were
 4 supported by fees generated from the hospitals and those
 5 of administrative fees. Dues-based organizations as
 6 opposed to administrative fees-based organizations.

7 Hospitals and the continuing challenges that
 8 they have had have looked for ways over the years
 9 through shared services activities and through group
 10 purchasing organizations to reduce administrative costs.
 11 Particularly in the seventies and eighties, group
 12 purchasing organizations moved towards fees with the
 support of administrative fees. This was a major trend in the
 1970s and 1980s. The shift from administrative fees to
 group purchasing organizations was a burden reduction from the

1 organization provides for their organizations.

2 Also, they provide rebates and distribution of
3 the fees back to the individual hospital. Some of those
4 fees are used for the uncompensated care issues and to
5 provide greater services. Finally, for those fees, they
6 are providing quality, safety and standardization.

7 So, I guess my response in summary to your
8 comment is that they do both. They provide a discount
9 and they also provide an administrative fee that offsets
10 those costs for the hospitals, and that's why hospitals
11 are so wildly supportive, we believe, of the function,
12 either group purchasing activity or through IDNs.

13 MS. DeSANTI: Thank you.

14 Mr. Clark?

15 MR. CLARK: I guess from my perspective,
16 hospitals paying the fee either directly or indirectly,
17 but that three percent aggregated at the GPO level then
18 allows that administrative burden of tracking and
19 managing sales volume rebates, the whole nine yards, to
20 be handled in one place on a group level much more
21 efficiently than if I had to be worrying about that and
22 every one of my 22 hospitals and if every hospital had
23 to do on their own, then the burden of just the
24 administrative burden of handling that process would be
25 very difficult. So, that's just another service that

1 has been aggregated at the group level.

2 MS. DeSANTI: Mr. Holden?

3 MR. HOLDEN: I think we can look at fees and
4 say, well, you know, aggregating purchasing into one
5 location will certainly save hospitals and networks
6 money. The question is should it be on the backs of the
7 vendors? And I think in an ideal world it would not be
8 or that fee would come from savings rather than the
9 selling of the actual product. But we're not living in
10 an ideal world and we understand in the whole spectrum
11 of the marketplace that hospitals are under very heavy
12 constraints trying to stay profitable or at least break
13 even.

14 So, I think the concern with the fees are one,
15 where do they come from, and by them coming from the
16 actual sale of the product, a three percent fee on how
17 much product goes through the door versus the how much
18 you save a hospital, I think that creates some
19 disincentive for GPOs to actually save money.

20 If on a contract you have company A and you're
21 purchasing a million dollars worth, and company B can
22 actually bring that product, the same product or
23 equivalent product to the hospitals for less money, the
24 GPO collects less money, it collects less fees. That's
25 the nature of the dynamics.

1 So, for these GPOs to give away money by signing
2 contracts with vendors for lower pricing is a
3 disincentive to do it. So, there's some concern with
4 that fee. Again, speaking to the nonlinear pricing,
5 these are not based on volume, they're based on
6 compliance percentages, not on volume. And I think
7 therein lies part of the problem.

8 One final thought, while the GPOs, the larger
9 ones, you know, Novation and Premier, do provide some
10 very good services in consolidating, I think there's
11 some concern. I mean, if you look at the financial
12 incentives for some of the mid-level and senior-level
13 managers at Premier and Novation in the way they receive
14 their salaries. You know, these guys are making a half
15 a million dollars a year to over a million dollars a
16 year to be executives in these organizations and yet the
17 primary purpose is to save the health care system money.
18 I think we should be questioning that as well.

19 MS. DeSANTI: Professor Burns?

20 MR. BURNS: Yeah, let me just follow up on what
21 Larry mentioned in an earlier comment by Steve about
22 economies of scale. The hospital industry has been
23 searching for the elusive economies of scale for the
24 last 20 years, and that's why they formed hospital
25 systems, that's why they formed hospital networks,

1 that's why they have these large integrated delivery
2 networks, and almost all of the econometric evidence to
3 date points that those economies of scale are limited
4 and achieved at a very early size. And we actually
5 published a review of this in Health Affairs two months
6 ago.

7 Given that, hospitals are hard-pressed to find
8 economies in other areas of scale, the one area where
9 they seem to have found it has been in the group
10 purchasing side, which is on the administrative side
11 rather than the clinical side, where hospitals have
12 never been able to achieve any economies.

13 So, group purchasing serves as the one tangible
14 area that I can point to where hospitals have achieved
15 some economies of scale. Now, going to Larry's comment
16 about exerting it on the small device manufacturers,
17 hospitals, if you go back to my slide on the health care
18 value chain, hospitals are squarely in the middle of the
health care system. On the one side, what we call

1 care. That game has pretty much played itself out.

2 Now hospitals are using their GPOs, and acting
3 independently as integrated delivery networks to push on
4 the other side of the value chain, upstream toward the
5 manufacturers and the distributors. This is a game that
6 everybody in the health care system plays, okay?

7 Unfortunately for the small manufacturers, when
8 everybody else is consolidating, you're at a relative
9 disadvantage. But this is what has been taking place
10 throughout the entire health care system. You look at
11 manufacturers, you look at distributors, you look at
12 hospitals, you look at physician groups, you look at
13 managed care organizations, you look at employers who
14 are forming purchasing coalitions, everybody has gotten
15 big to push back on people upstream and downstream to
16 get the best rates they can. This is just the way our
17 system works. Smaller manufacturers are at potentially
18 a disadvantage at that.

19 Now, the one thing I would say is that on the
20 product manufacturing side, we have the most innovative
21 set of product companies in the world, probably fueled
22 by our reimbursement system, but I don't see any
23 diminution in the innovativeness in the medical device
24 and technology sector, a lot of those firms form,
25 develop and proceed and then get bought up by the larger

1 manufacturers. That clearly exists, but I don't see
2 innovation having been impeded in some portion of the
3 medical device sector.

1 of potential with a better mouse trap. Smaller
2 companies with a true, novel break-through technology
3 need not pass through the GPOs' doors to get attention.
4 They can go directly to the chiefs of cardiology,
5 radiology, orthopedic surgery, so forth. They can be
6 published in peer review journals. They can have
7 Internet sites. There are many ways to access the
8 decision makers, especially for the high-end
9 technologies that will demand those as chiefs of
10 cardiology, other leaders, other clinical so forth
11 leaders. That's what gains attention.

12 Secondly, insofar as demonstrating how good a
technology is, whether it's safety, efficacy, cost

1 value of your technology to the people that will try to
2 acquire it, whether it's through a GPO or otherwise.
3 The avenues are not closed for innovation.

4 MS. DeSANTI: Others who want to make a final
5 comments from Mr. Clark, we'll start with you.

6 MR. CLARK: Well, I would just echo what was
7 just said. I don't feel any lack of new technology
8 coming through our doors, people seeking our attention,
9 and visiting with our physicians. I think that door is
10 open, as I mentioned earlier, I think in our experience,
11 the product contract selection process is an upward
12 process, and I believe that properly done, both the
13 manufacturer, small, large or otherwise, and we as the
14 provider benefit from the process, and I believe that we
15 ultimately, directly or indirectly, end up paying that
16 fee.

17 So, I think if it's approached properly, we
18 don't lose contact with those small innovators. There
19 are many of them.

20 MS. DeSANTI: Mr. Manley?

21 MR. MANLEY: Again, I will pretty much echo what
22 everybody else has said. Technology is an issue that's
23 solved best at home and solved best at the hospital. We
24 have not ever seen an instance where technology has been

1 systems, most hospitals don't try to act as their own
2 GPOs, and those who have in the past often failed. Like
3 distributors. Nobody wants to do what distributors do.
4 They make a one percent margin or less, why do this?
5 But they provide a value-added. I think GPOs do, too,
6 to some extent.

7 MS. DeSANTI: Professor Latham?

8 MR. LATHAM: I ate lunch upstairs yesterday at
9 the FTC cafeteria.

10 MS. DeSANTI: Please forgive us.

11 MR. LATHAM: And believe it or not, I didn't
12 feel that I was faced with a lack of choices about
13 things that I could eat, but is there a world in which
14 the menu up there might be a little bit bigger?
15 Certainly. I don't know how you feel the lack of
16 technologies that have not made it into a marketplace.
17 I think we have to think when we're thinking about what
18 the FTC should be looking at, and what the guidelines in
19 this area should address themselves to, we do have to be
20 thinking along the lines that Commissioner Riley was
21 talking about, about the existence of possible
22 uncomfortable trade-offs between current short-term
23 price advantages for hospitals and longer term and
24 perhaps more speculative benefits to patients down the
25 road from innovation.

1 It's great that there's a lot of innovation
2 going on now. The question is whether there might be
3 more in the absence of certain kinds of contracting. I
4 would add finally, I didn't mean to be so harsh on GPOs
5 when I came today, I meant to be talking only about the
6 structure of the guidelines. I want to say that there
7 are obviously hundreds of GPOs, and the various
8 allegations that I have been sort of recounting are
9 attached in the press at least to only a very, very few
10 of them. I think there is no doubt but that GPOs save
11 hospitals a great deal of money and perform a really
12 valuable service. As the GAO study showed, particularly
13 to the small hospitals that just don't have the
14 wherewithal or the scale to do this for themselves.

15 So, in that sense, I applaud it, but I do wish
16 that the FTC would look at whether in the presence of
17 GPOs helping and gaining market share and doing joint
18 purchasing, whether there's a threat to innovation from
19 specific contracting practices that are associated with
20 only a few of the GPOs out there.

21 MS. DeSANTI: Mr. Holden?

22 MR. HOLDEN: I would just echo a lot of what was
23 just said. I think the problem that we see is inherent
24 in the fact that you have two GPOs, the ones that we are
25 hearing about the New York Times, the ones that we are

1 talking about in the Senate hearings, that those are
2 also the two GPOs that are controlling the vast majority
3 of the marketplace. So, it begs the question, have they
4 reached that point where they are creating some problems
5 within the marketplace?

6 I would just point out that 90 percent of the
7 innovation in the medical device field comes from
8 companies of 50 employees or less. The companies that
9 are getting GPO contracts, if you look at that suite A
10 bundle I mentioned all those contracts, 3M, Beckton
11 Dickinson, Bard, Ethicon, which is J&J, okay, that's
12 who's getting the primary. That's who's getting the
13 lion's share. These are the top 20 medical device
14 companies in the United States.

15 Are we losing innovation? Those top 10
16 companies, if you look at their annual reports, they
17 don't do R&D anymore, they buy out small companies. If
18 those companies aren't there for them to buy out,
19 innovation is being harmed. It's being harmed because
20 there are groups of GPOs, primarily Premier and Novation
21 and some of the contracting practices of others that are
22 excluding small and innovative companies from the
23 marketplace.

24 It's not always that break-through technology.
25 Again, a large portion of the medical device field, it's

1 incremental increases in knowledge that changes people's
2 lives, and you're going to lose that if there's not some
3 sort of change in the market dynamic.

4 MS. DeSANTI: Mr. Betz?

5 MR. BETZ: Thank you.

6 First of all I would like to say, and I think I
7 speak for the rest of the panel, when I say thank you to
8 the FTC and particularly to Mr. Hyman for all of the
9 arrangements that have been made, and on behalf of my
10 organization anything that we can do to assist you in
11 further workshops or additional presentations, don't
12 hesitate to holler at us.

13 I would just like to close on the matter of
14 access and innovation, if I could. I would like you to
15 just keep a couple of thoughts in your mind. First of
16 all, you need to differentiate between high clinical
17 preference items, and a whole lot of me-too products.
18 If I am out in a garage somewhere creating what I
19 consider to be an innovative product, in my eyes, it may
20 be an innovative product, but to the clinicians that
21 evaluate on behalf of group purchasing organizations,
22 for the hospitals, they may not think this is an
23 innovative product. They may think that it is simply a
24 me-too. So, I think we need to differentiate those in
25 our thinking.

1 I would also ask you, I understand how difficult
2 it is for a small manufacturer as it is in any industry
3 to succeed; however, some of the charges that have been
4 made have come from companies that I find it interesting
5 to look at their shareholder lists and also their SEC
6 filings about the contracts that they do have. On the
7 one hand they compete and complain about group
8 purchasing organizations, but yet in their filings for
9 investors, and with the SEC, they tout their
10 relationships with these same organizations.

11 Group purchasing organizations do push back for
12 hospitals against manufacturers. Some of which I
13 believe after some study do demonstrate oligopolist
14 tendencies. I think that hospitals have a true value in
15 this country and we are their advocates and will
16 continue to be such, but I do not know of particular
17 examples of products that are being foreclosed from the
18 marketplace.

19 We've heard allegations that certain products
20 are being foreclosed from the marketplace by group
21 purchasing organizations. It is clear, I think, from
22 some of the comments that have been made here and from
23 the literature that the market in which groups operate
24 is highly competitive.

25 In conclusion, keep just one thing in mind, if a

1 group purchasing organization does not provide products
2 that the member hospitals demand, another group
3 purchasing organization will. They are very highly
4 competitive with one another. Individual hospital
5 members of these organizations have considerable choice
6 in their purchasing decisions of the best products at
7 the best price for the patients that we are here to
8 serve.

9 Thank you.

10 MS. DeSANTI: Thank you all very much. I really
11 appreciate the wealth of experience and information that
12 this panel has brought to us. We will reconvene at
13 1:15, and the FTC does have a cafeteria, it's up on the
14 seventh floor, if you want to go for a swift lunch. I
15 actually can recommend it.

16 Thank you again.

17 (Whereupon, at 12:20 p.m., a lunch recess was
18 taken.)

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AFTERNOON SESSION

MR. HYMAN: If everyone can take their seats,

1 how important I think this kind of activity is.

2 Unfortunately, I can not attend many of the
3 sessions of this program or the other programs that
4 we have had here, but I promise you that I do read
5 transcripts, and I read presentations, and they are
6 tremendously helpful to me.

7 I can not help digressing just a minute today
8 and thinking about a meeting we had in this very

1 Bear in mind that the famous Standard Oil case
2 had been decided just three years before. The general
3 public thinks of the Standard Oil case as the case that
4 broke up the Standard Oil trust, and it is important for
5 that, but it is also important for the creation of a
6 so-called Rule of Reason in antitrust law. You have
7 to determine whether or not a particular practice was
8 legal or illegal based on a variety of factors.

9 There was this level of uncertainty in the
10 business community about what is legal and what is not
11 legal. One of the ideas behind the creation of the Federal
12 Trade Commission is we will have a body of supposed
13 experts to give guidance. I don't think of the expertise
14 as residing where I am. I think of the expertise as
15 being in the staffs that we've accumulated in this
16 building, who try to inquire as to what might or might
17 not be reasonable and then provide some guidance to
18 the outside world.

19 That is what these meetings are all about. This
20 particular aspect of our mission was somewhat neglected
21 for many years, and to his great credit our former
22 chairman, Bob Pitofsky, revived it in 1995 with a series
23 of very extensive and comprehensive hearings on
24 international, high tech competition. That tradition
25 has been expanded upon by Tim Muris, the current chairman.
26 I can't tell you how gratifying it is to me personally

1 and how important I think it is that the Federal Trade Commission
2 continue these efforts.

3 Now, what do we do with the learning that's
4 accumulated in this room. Well, there are a number of
5 things we do. It informs our prosecutorial judgments.
6 We bring cases or we don't bring case based on what we
7 learn here. It informs comments that we make to other
8 government bodies at the state or local level. We are
9 very frequently asked to comment on various matters of
10 concern, and we draw on information that we get from
11 workshops like this one and others.

12 We just are winding up a very significant one
13 on the patent antitrust interface, for example. We have
14 got one coming up on problems caused by public and
15 private impediments to the development of ECommerce.
16 All of these issues are issues that do not just concern
17 the Federal Trade Commission and our particular authority
18 but concern a variety of other government authorities.
19 To the extent that they will listen to us, we provide our particular
20 perspective on these issues, informed by these meetings.

21 I think that those of you who have attended this
22 meeting, or have attended some of the others we have had

1 -- whatever your responsibilities may be in the
2 public or private sector -- walk away with a renewed
3 appreciation of the difficulties and the complexities of
4 a lot of issues that we deal with.

5 We say our competition policy and really our
6 consumer protection policy is informed by economics, but
7 the economics of the health care business are somewhat
8 odd. You have got the third-party payor problem. You
9 have got the problem that an identifiable human life
10 is regarded as having almost infinite value. It
11 makes it very, very difficult to think of cost effective
12 ways to deal with health care because the minute it's personalized
13 -- either because of something you read
14 in the newspaper or because of your own personal
15 experience -- economics goes out the window.

16 So, there are unusual challenges in dealing with
17 this particular subject. I think that even if we
18 can not provide bottom line solutions as a result of
19 a meeting like this, at least the debate will be
20 enriched and people will have a heightened appreciation
21 for what the other guy has got to say.

22 I just have to tell you that the longer I live
23 and the more experience I have in the world at large,

1 the less sure I am that I am right about anything. For me,
2 the process of growing up and maturing as a human being
3 is the process of appreciating how difficult and
4 how complicated problems are in this world.

5 So with that, I wish you well. I hope you have
6 a good session this afternoon. I can not be here but,
7 as I said, I promise you, I will read what you have to
8 say. Thank you.

9 (Applause.)

10 MR. HYMAN: Thank you, Commissioner Leary. Our
11 first speaker of the afternoon is Michael Wroblewski
12 from the Office of Policy Studies, who is the
13 principal, author along with lots of other people at the
14 Commission of the Generic Drug Study, copies of which
15 are outside -- there seem to have been a run on the
16 market, but we're trying to get some more.

17 MR. WROBLEWSKI: Thank you, David, and good
18 afternoon. I was asked to give a 15 minute thumbnail
19 sketch of the Generic Drug Study that the Commission
20 just released in July of this past year that really
21 reviewed experience to date under the Hatch-Waxman Act.

22 As most of you already know, the Hatch-Waxman
23 Act established a regulatory framework that sought to
24 balance incentives for continued innovation by
25 brand-name companies and to encourage opportunities for

1 market entry by generic drugs.

1 ANDA, an Abbreviated New Drug Application is
2 what a generic drug applicant files with the FDA to get
3 approval of its generic version of a brand name drug
4 product. In that ANDA, it has to show that its product
5 is bioequivalent to the brand name product that it is
6 making a generic version of. It gets to rely on the
7 safety and efficacy data of the brand name product. It
8 doesn't have to prove that again, but it just has to
9 show bioequivalence.

10 One part of the application of the ANDA is a
11 Patent Certification, and what we're going to be talking
12 about today are really the Paragraph IV certifications,
13 and those are the certifications that the brand name or
14 the generic applicant has to make relating to the
15 patents that cover the brand name product.

16 Now, Paragraph IV certification is one in which
17 the generic applicant says that the patents are either
18 invalid or not infringed by that particular ANDA.
19 Obviously by its name Paragraph IV certification, there
20 are paragraph I, II and III certifications that we're
21 not going to talk about this afternoon that really deal
22 with patents that have already expired or generic
23 applicants that seek to enter the market prior or right
24 after the patents expire.

25 The Orange Book, the Orange Book is where the

1 general public can go and look up a brand name product
2 and find which patents cover that particular brand name
3 product.

4 The 30-month stay, the 30-month stay is really a
5 30-month stay of FDA approval of an ANDA. It is
6 invoked if a brand name company receives notification by
7 the generic applicant of an ANDA that it has filed with
8 the FDA that contains a Paragraph IV certification. If
9 the brand name company files suit, patent infringement
10 suit, within 45-days, the FDA is prohibited or is stayed
11 from approving that ANDA for 45 days from that notice.

12 Last the 180-day exclusivity is awarded to the
13 first generic applicant to file an ANDA containing a
14 Paragraph IV certification. The 180-day exclusivity
15 starts to run on one of two events, either when the
16 generic applicant begins commercial marketing or a court
17 decision.

18 During this time period, the FDA is prohibited
19 from approving a subsequent or a second or a third or a
20 fourth generic applicant for the same drug product.

21 Let me give you a quick little scope background
22 of the Commission study. We announced in October of
23 2000 our intent to undertake a study of how generic drug
24 competition has developed under Hatch-Waxman. We
25 undertook it really for three reasons: One is that at

1 that point the Commission had taken law enforcement
2 action against some allegedly anti-competitive
3 agreements between brand name companies and generic
4 applicants, and we wanted to see if those agreements
5 were isolated instances or were they more typical.

6 We had been asked by Congress to look at this
7 issue. And over the next several years, there's a
8 substantial volume, a sales volume of brand name drug
9 products that are coming off patent. The Commission
10 wanted to ensure that there were no roadblocks to
11 generic drug competition developing for those brand name
12 products.

13 We received clearance from OMB last April, April
14 2001 to conduct the study. We issued nearly 80 special
15 orders pursuant to Section 6 (b) of the FTC Act to brand
16 name and generic companies. We focused the special
17 orders on brand name drug protects that were the subject
18 of Paragraph IV certifications filed by generic
19 applicants, and we looked at those NDAs, those New Drug
20 Applications, that had a Paragraph IV filed against it
21 between 1992 and the end of 2000.

22 That resulted in a 104 drug products that are in
23 our study as measured by unique NDA numbers, and they
24 include such as blockbuster drugs such as Cardizem CD,
25 Claritin, Pravachol, Xanax, Zantac, Zocor, Zoloft.

1 The responses to the special orders were
2 generally completed by the end of last year, and we
3 produced the study, and we released it this July.

4 The rest of the talk I want to talk about first
5 will be the 30-month stay and then the 180-day marketing
6 exclusivity provision. The study sought to determine
7 the frequency by which brand name companies sued generic
8 companies within that 45-day period, which then invokes
9 that 30-month stay.

10 As I mentioned, this is actually figure 2.1 that's
11 on page 15 of the report, so if you want to look through
12 it in here. As I indicated there were 104 NDAs that are
13 part of the study. For 29 of those brand name drug
14 products, the NDA holder, the brand name company, did
15 not sue the generic applicant.

16 FDA approved those ANDAs on average in 25
17 months and two weeks 25 months, 14 days, for FDA to
18 approve those 29 ANDAs that had not been sued but had
19 contained a Paragraph IV certification.

20 In 75 instances, the brand name company sued the generic
21 applicant. As of June 1, this is when all this
22 data is taken as of, a snapshot is of then. As of June 1,
23 22 of those patent infringement suits are still pending.
24 In 15 of those the initial 30-month stay has not yet

1 patents.

2 This compares to only 1 of 9 blockbuster drug
3 products as to which the brand name company filed suit
4 against the first generic applicant prior to 1998 for
5 more than three patents, and usually only sued on one or
6 two patents, in most cases only one. In the future this
7 may portend a result that the patent litigation will take
8 longer than the 25 months and two weeks for the
9 litigation to be resolved.

10 The second phenomena that we observed was an
11 increase in the listing of patents in the Orange Book
12 after an ANDA has been filed. We noticed that it has
13 occurred since 1998, and it's happened for eight drug
14 products. By listing patents in the Orange Book after
15 an ANDA has been filed, brand name companies can obtain
16 additional 30-month stays of FDA approval, and this can
17 occur under the following scenario:

18 An ANDA has been filed for a particular drug
19 product. Brand name company lists an additional patent
20 in the Orange Book. The generic company makes a new
21 certification, a Paragraph IV certification saying that
22 that particular patent is either invalid or not
23 infringed. It then has to notify the brand name
24 company.

25 It notifies the brand name company. The brand

1 name company sues within 45 days. An additional
2 30-month stay is then instituted. So what happens is you
3 have 30-month stays that are now stacked upon each
4 other, and for these eight drug products where this
5 occurred, the additional delay of FDA approval, beyond
6 the first 30 months, has ranged from four to 40 months.

7 In all four cases so far with a court decision
8 on these later listed patents, the patent has been found
9 either invalid or not infringed by the ANDA.

10 The interesting thing is in these eight cases,
11 most of the later-issued patents raised questions about
12 whether the FDA's patent listing requirements have been
13 met. The study describes three categories of patents
14 that raise significant listability questions.

15 These are all described in Appendix H in
16 excruciating detail, so if you want to read further
17 about them, you can. Briefly they are patents that may
18 not be considered to claim the drug formulation or
19 method of use; a product by processed patents; or patents
20 that constitute double patenting.

21 The problem is that recent court decisions have
22 held that Hatch-Waxman doesn't provide generic
23 applicants a basis to challenge the listing of any of
24 these patents.

25 So to remedy the harm caused by these late

1 listed patents, the study recommends that Congress
2 permit only one automatic 30-month stay per drug
3 product, per ANDA to resolve patent infringement
4 disputes over patents listed in the Orange Book prior to
5 the filing of an ANDA.

6 This we thought was reasonable, one, because as
7 we've noted that historically it took FDA about 25 and a
8 half months to approve an ANDA with a Paragraph IV
9 certification that hadn't been sued. It took about 25
10 and a half months and may be taking longer for a
11 District Court to obtain a decision or for a District
12 Court decision to be rendered, and so that the first
13 30-month stay wouldn't cause any additional delay other
14 than what would occur otherwise.

15 We were thinking that this would eliminate most
16 of the potential for improper Orange Book listings to
17 generate unwarranted 30-month stays. The study also
18 recommends that Congress clarify when brand name
19 companies can sue generic applicants for patent
20 infringement by overruling the Allergan case.

21 We raised some additional concerns about patent
22 listings. As I mentioned earlier, currently the FDA
23 doesn't review the propriety of patents listed in the
24 Orange Book, and courts have ruled that applicants don't
25 have the ability to challenge one of them, to seek a

1 delisting of them.

2 The lack of such a mechanism can have some real
3 world consequences in that the Commission is aware of at
4 least a couple instances in which a 30-month stay, the
5 first 30-month stay has been generated solely by a
6 patent that raised legitimate listing questions. At a
7 minimum, it appears useful for the FDA to clarify its
8 listing regulations.

9 Another remedy that may warrant consideration
10 would be to permit a generic applicant to raise
11 listability issues as a counterclaim in patent
12 infringement litigation that's already in progress. In
13 this way, the dispute could be resolved in the same
14 forum, in the same District Court that the patent
15 infringement litigation is already underway.

16 I'm going to switch now to the 180 days and give
17 you first a couple of facts about how frequently the 180
18 days has been awarded. Prior to 1992 it had been
19 awarded for three particular drug products. Between
20 1993 and 1997, it wasn't awarded at all, and since 1998,
21 the FDA has granted the 180-day exclusivity for 31 drug
22 products.

23 As I mentioned earlier, the running of the 180
24 days can be triggered either by commercial marketing or
25 by a decision by the Court. In 19 instances, it was by

1 the commercial marketing by the generic drug applicant,
2 and in the other 12 instances it has been a court
3 decision that has triggered the exclusivity.

4 In most instances, the generic applicants have
5 waited to enter the market until at least a District
6 Court has held that the patent covering the brand name
7 drug product was invalid or not infringed by the ANDA.

8 The recent antitrust issue that has arisen is
9 how these patent settlements can affect generic entry.
10 As I mentioned earlier in that schematic of how the 104
11 cases have been decided, remember there were 20 cases
12 that have settled, so there were 20 final settlement
13 agreements, and they really broke down into three types
14 of agreements.

15 The first type of agreement was one that
16 involved a brand payment. Typically there was a brand
17 payment from the brand name company to the generic
18 company, and the generic company would not enter, in
19 most instances, until the patents had expired, in one or
20 two instances, slightly before the patent had expired.

21 Seven of the agreements were license agreements
22 where the brand name company licensed its patents to the
23 generic applicant in exchange for a royalty payment
24 based usually on net sales or some type of sales figure,
25 so that the generic applicant could use those patents

1 prior to patent expiration and enter the market prior to
2 patent expiration.

3 The last two agreements we saw were supply
4 agreements where the brand name company would supply the
5 generic applicant with its products. So that the generic
6 applicant would be marketing the brand name product
7 rather than seeking approval of its product under the
8 ANDA.

9 The problem is that 14 of these agreements had
10 the potential to park the 180-day exclusivity for some
11 period of time, and what I mean by that is that because
12 it was a settlement agreement, there wasn't going to be
13 a decision of a court, at least with that first
14 applicant, and if there was a delay in when the generic
15 applicant would begin to market, it would preclude FDA
16 from approving any subsequent eligible generic
17 applicants that were ready to come, so it could act as a
18 bottleneck.

19 To mitigate against the possibility of this
20 happening, the study recommends that Congress enact S
21 754 which is the Drug Competition Act as introduced by
22 Senator Leahy to require brand name companies and
23 generic applicants to provide copies of certain
24 agreements to the Commission and to the Department of
25 Justice.

1 We also have three minor recommendations based
2 on the conduct observed. The first one is to clarify
3 that the commercial to marketing trigger for the 180
4 days would be triggered, and I mentioned earlier that
5 there were two agreements where it was a supply
6 agreement where the brand name company was supplying the
7 generic company with product. If that's the commercial
8 marketing that the generic company is engaging in, that
9 should constitute commercial marketing such that it
10 triggers the 180 days, and it doesn't preclude FDA from
11 approving a subsequent eligible applicant.

12 The second and third clarifications really deal
13 with, if you have somebody who's second or third ready
14 to go, the 180 days shouldn't be acting as a bottleneck.
15 So the second clarification is to say that if there's a
16 court decision, regardless of whether it's the court
17 decision hearing the first applicant's court case, that
18 that court decision would constitute a court decision to
19 trigger the 180-day exclusivity.

20 The last one is to clarify that a court decision
21 dismissing a declaratory judgment action for lack of
22 subject matter jurisdiction constitutes a court
23 decision, and that's really what happened in the Ticlid
24 case involving Teva and Hoffman La Roche.

1 In conclusion, Hatch-Waxman has been generally
2 successful in encouraging generic entry, but the
3 30-month stay and the 180-day marketing exclusivity
4 should be amended to ensure that the provisions are not
5 gained to delay or deter generic entry.

6 Thank you.

7 MR. HYMAN: Thank you, Michael. Our next
8 speaker is Jarilyn Dupont from the Food and Drug
9 Administration. Jarilyn informed me I think late
10 yesterday that I erroneously capitalized the P in
11 Dupont, and she is not related to the wealthy DuPonts,
12 so I managed to correct it on her name tag but pretty
13 much nowhere else.

14 MS. DUPONT: Good afternoon. Although I'm
15 following Mike's commentary, originally I was not
16 supposed to, so I don't want to mislead anyone and think
17 that I'm going to respond to the FTC recommendations in
18 their report. I assure you that's not my function at
19 this particular time.

20 We clearly appreciate the work that's been done
21 by FTC, and we certainly feel that it has confirmed some
22 of the perceptions that FDA has had with respect to the
23 increased number of patent filings and the increase
24 in related lawsuits.

25 With respect to FDA action on any of the FTC

1 recommendations, we have two things that are going on.
2 We have a citizen's petition that FTC filed with us last
3 May, and that will be responded to. I know they're
4 wondering when, and it will be at some point in the
5 future, as everyone knows how quickly we do respond to
6 citizen's petitions. We will be responding to that and
7 working on it. I think part of it was we were waiting
8 for the report to come out.

9 The second thing is last year's appropriations
10 bill required us to file the response, a report to
11 Congress with respect to the FTC report eight months
12 after the report was filed, which puts it at about
13 March. The new appropriation bills are trying to
14 shorten that time, but we are working on that response,
15 and we will be filing a report to Congress on the FTC's
16 recommendations that are in the report.

17 Let me start by saying, going to the bulk of my
18 speech, I'm afraid Mike gave you part of it, so I think
19 I'm probably going to bore you on some of this, and for
20 those of you who are experienced with the FDA process,
21 you may be doubly bored, but I'm going to go into a
22 little more detail about the whole system of the Orange
23 Book.

24 As I told someone before this, the most critical
25 point on this is why is it called the Orange Book, and

1 so that every one will know and everyone has asked that
2 no other colors were available in the printed copy, and
3 therefore they picked orange, and it is orange even on
4 the web site.

5 If most of you don't know the correct title of
6 it, it's the Approved Drug Products for Therapeutic
7 Equivalence Evaluations, and it includes other
8 information in addition to these patent listings, but it
9 is obviously commonly known as the Orange Book, and it's
10 difficult to getting away from calling it that, if
11 you're familiar with it.

12 With respect to our perspective on generics and
13 branded pharmaceuticals, obviously the agency and the
14 administration are committed to assuring that the
15 approval process works well and is balanced. As Mike
16 pointed out the original act had, it balances both
17 innovation of new drugs against access to generic drugs,
18 and that is a very hard sort of avenue to take, and it's
19 very difficult to do that to everyone's satisfaction.

20 I don't think we'll ever get it to everyone's
21 satisfaction, but it's certainly something we're trying
22 to accomplish.

23 Let me go to the process. Under the FDNC Act,
24 the provisions which were implemented by the Drug Price
25 Competition and Patent Restoration Act of 1984, which is

1 either known as Waxman-Hatch or Hatch-Waxman, and since
2 I have a former Waxman staffer sitting in the audience
3 and a current Hatch staffer sitting in the audience, you
4 can all take your pick as to what you call it.

5 Those particular provisions require that as part
6 of a New Drug Application for an innovator or supplement
7 to a New Drug Application, information on any patent
8 that claims the pending or approved drug or a method of
9 using the drug and for which a claim of patent
10 infringement could reasonably be asserted must be filed

1 someone could file an action with respect to these
2 particular patents.

3 The ANDA process permits approval of generic
4 versions of approved innovator drug products. That was
5 Title I of Waxman Hatch. The timing of the approval
6 depends in part on patent protections for the innovator
7 drug, and let me point out something that may not be
8 clear is that with respect to these generic applicants,
9 they can file them many months, whatever years, before
10 the patent expires, so that you will have this
11 particular patent -- excuse me, generic application
12 sitting there for some time before actually there may be
13 any movement on it, or there may be movement on it, but
14 it certainly can only get a tentative approval until the
15 patent or any exclusivities have expired with respect to
16 that particular patent or some of the other activities
17 occur, the court decisions, commercial marketing or the
18 court decisions are taking place.

19 Consequently, what happens is is when they file
20 an application, however early it is, they must contain a
21 certification for each patent listed in the Orange Book,
22 and there's four different certifications. I know we've
23 concentrated on Paragraph IV, but there's one other that
24 actually is relevant to this, but the four are that the
25 required patent information relating to such patent has

1 not been filed; that such patent has expired, which is
2 number II.

3 Number III is that the patent will expire on a
4 particular date; and IV is that the patent is invalid or
5 will not be infringed by the drug for which approval is
6 being sought.

7 The last is that Paragraph IV certification.
8 The important part here is that the third one is that
9 the patent will expire, and what happens obviously is
10 that a generic will file that and say the patent will
11 expire on a certain date, and in the meantime, a new
12 patent will be filed for listing in the Orange Book to
13 which they then have to then file a Paragraph IV
14 certification. So they have to amend it basically and
15 file a Paragraph IV certification.

16 If they submit this Paragraph IV certification,
17 they've got to notify the NDA holder, and the NDA holder
18 then has 45 days within which to file a patent
19 infringement action. If they file within that 45 days,
20 then the 30-month stay is imposed. If the court
21 decision is before the end of the 30 months, then the 30
22 months expires before 30 months.

23 If no action is filed, again as I explained, you
24 can issue a tentative approval for the drug, but it
25 cannot be a final approval or a complete approval

1 patent information is withdrawn or amended by the NDA
2 holder, and as you know that has led to quite a lot of
3 litigation.

4 We don't assess whether or not the patent claims
5 an approved drug or whether the claim of patent
6 infringement could reasonably be made against an
7 unauthorized use of the patented drug.

8 As we've maintained since the implementation of
9 the Act, we have no expertise or resources with which to
10 resolve complex questions of patent coverage. The
11 agency role is totally ministerial, and the courts have
12 upheld that this ministerial role since forever -- most
13 recently in July of 2002.

14 The process of patent certification, the notice
15 to the ANDA holder and patent owner, the 45-day waiting
16 period, possible patent infringement litigation and the
17 statutory 30-month stay does mean that there is the
18 possibility of considerable delay in the approval of an
19 ANDA.

20 These delays, the type of patents that are
21 submitted and our role in maintaining the Orange Book
22 have prompted much litigation, the Generic Drug Study
23 and much Congressional interest. There are several
24 pieces of legislation going through right now that do
25 address some of this.

1 As I noted before, we're working on the report
2 to Congress and a response to the FTC's citizen's
3 petition. When these are available, there will be more
4 information on FDA's position with respect to the
5 recommendations. Thank you.

6 MS. MATHIAS: I believe next we have the panel,
7 and let's get everyone pulled up and get that set up to

1 PANEL 4: GENERICS and BRANDED PHARMACEUTICALS

2

3 Panel Members

4 Ashoke Bhattacharjya, Jensen Pharmaceuticals

5 Greg Glover, Ropes and Gray

6 Bill Schultz, Generic Pharmaceutical Association

7 Sarah Lock, AARP

8 Amanda McCluskey, Families USA

9 David Reiffen, Treasury Department

10

11 Michael Kades, FTC, Moderator

12

13 MR. KADES: Good afternoon. It's not
14 surprising that this panel is about pharmaceutical
15 industry and competition. I'll be moderating it. My
16 name is Michael Kades. I'm an attorney in the health
17 care division of the Bureau of Competition. Hopefully
18 you will hear little from me and most from the
19 panelists.

20 Each of the panelists will have ten minutes for

1 Just so you'll know, the order of presentation
2 will be alphabetical, so you can't read anything from
3 the tea leaves of the order of the presentation, so I
4 think with that, we'll begin.

5 Our first speaker is Ashoke Bhattacharjya who is
6 the Senior Director of Business Information for Jensen
7 Pharmaceuticals, which is a wholly owned subsidiary of
8 the Johnson & Johnson Company.

9 DR. BLATTACHARJYA: Good afternoon. I would
like to thank the FTC and David Hym0dhnati72en

1 as well as the other legal issues, but I will focus, as
2 I said earlier, on the economic aspects.

3 I will also talk a little bit about the economic
4 impact of the Hatch-Waxman Act and other market dynamics
5 that have accompanied the time period since its
6 inception. In particular, I will spend a few minutes on
7 the dynamics and variety of competition. This, I think,
8 is the crux of my presentations in any case, and follow
9 up with some findings from key academic and government
10 sources, including the FTC report itself, and then
11 briefly allude to some general J&J, Johnson & Johnson
12 positions on Hatch-Waxman reform.

13 Overall, there are some facts in here that may
14 be familiar to some, but I think they something bear
15 reiteration and have been already alluded to in the FTC
16 report, but the market has grown tremendously over time,
17 and the question is, and this is an interesting issue
18 which often gets drowned out in some of the rhetoric
19 that the companies sort of discuss: What has contributed
20 to the tremendous explosion of the health care market
21 overall and the growth in expenditure in pharmaceuticals? Without
22 going into a lot of detail, what will be
23 available on the web site later on, the key point
24 recognizes that prescription drugs account for about 9.7 percent of
25 overall health care expenditures at this
26 point in time.

1 If you look at historical trend going back all
2 the way back to 1960, it was about 10 percent in 1960.
3 It declined to about, I would roughly say, 5 or 6 percent,
4 and then it's climbed since, but it is at a level which
5 we have seen before, but more importantly, this growth
6 has been driven primarily in the last six years by
7 volume and mixed growth, and about one fifth of it is
8 attributable to price change over that period of time.

9 This is a key issue, which I think is actually
10 well documented and may be found in a number of sources,
11 including the one that is noted at the bottom in a
12 footnote.

13 The growth of pharmaceuticals is also
14 attributable to the dramatic impact on improving health
15 care as well as the cost effectiveness, which I think
16 has been talked about earlier during this workshop.
17 There's a growing body of evidence, both in the clinical
18 and the economic literature, on pharmaceuticals that are
19 cost effective, and relative to other forms of health
20 care interventions, they often end up reducing total
21 costs associated with an illness by replacing sometimes
22 less effective and more expensive treatments.

23 Indeed, the President's report from this year,
24 2002, alludes to this very fact in quite some detail,

1 and I direct you to page 182 in particular.

2 The growth of pharmaceuticals is also explained
3 by the tremendous increase in third-party insurance and
4 Medicaid versus out of pocket payments. It's about to
5 up to about 70 percent now if you combine the two versus
6 I think approximately 18 percent in 1970.

7 Again this is background. That's the sort of
8 the perspective. That's the context in which we can
9 evaluate quickly the Hatch-Waxman Act. Overall, the
10 existing Hatch-Waxman Act provides what we believe are
11 an appropriate set of incentives for innovation by
12 research based companies and for market entry by generic
13 pharmaceuticals.

14 I will not belabor the points in terms of the
15 data, but I think you've already heard the generics do
16 account for about 47 percent of all pharmaceutical
17 prescriptions now. This is up from about 13 percent in
18 1980, and 19 percent in 1984.

19 Market penetration by generics have become
20 increasingly rapid. There are several case. The most
21 spectacular in this particular context being the case of
22 Prozac where within one week, 80 percent substitution
23 occurred within at least the Merck Metro system.

24 The Congressional Budget Office has done a
25 study, I think it was done about a couple of years ago,

1 in 1998, and there's a lot of discussion in that study
2 on the impact of the Hatch-Waxman Act, the economic
3 impact. It's estimated there were 8 to 10 billion
4 dollars saved from generic substitution in the mid
5 1990s, and the study also concluded that expected
6 returns from marketing new drugs have declined 12
7 percent because of this act, and this is from the CBO
8 study.

9 As I said, in the few minutes that remain, the
10 crux of the idea is that there's more than just price
11 competition in this market. Price competition is clearly

1 The therapeutic competition, the notion of that
2 is that even for branded products that are on patent,
3 there are a tremendous amount of competition that is not
4 always fully appreciated certainly in general
5 discussions and certainly in the popular press, and
6 there's been a number of examples, and there's some
7 remarkable shifts in market dominance, even among
8 patented drugs.

9 I think the case of Lipitor is well known.
10 There was another product which was the first product,
11 Zantac, this goes back in time, which was a major
12 anti-ulcer drug that superseded the first drug in that
13 category, and they were all considered to be highly
14 innovative drugs, so clearly there's no first mover
15 advantage.

16 There's a tremendous amount of product
17 differentiation among brands and their attributes.
18 Patient tolerance and efficacy are not uniform, and
19 they're all well served by increased variety, and that
20 variety is provided by a number of branded products in
21 the therapeutic class, and that's a major source of
22 competition. There are also a number of publications on
23 this particular topic.

24 Then there's this dynamic or Schumpeterian
25 competition. This is the one that's in the President's

1 report. Specific examples that are cited in that report
2 is the case of PPIs, which is a class of GI or
3 gastrointestinal, anti-ulcer type products but advanced
4 called pump inhibitors, and they replaced H 2s, which is
5 the class of drugs like Zantac and Tagamet and the PPIs
6 like Prilosec and Prevacet and so on, and this
7 particular class came and replaced and supplanted an
8 existing therapeutic class, an established class, which
9 was on patent.

10 The supersession occurred before patent
11 expiration. This is a key point that one needs to
12 recognize, and there are other examples I think in the
13 case of statin versus calcium channel blockers may also
14 be a relevant one.

15 The costs of innovation versus imitation I think
16 is well discussed in some context, but I think I would
17 like to remind the audience and others that it's a long
18 and intensive drug development process that takes about
19 12 to 14 years. It's highly risky. Only about 20 in
20 5,000 compounds that are screened enter pre clinical
21 testing, and then about one in five clinical trials
22 receive drug approval, that go into clinical trials that
23 receive drug approvals.

24 The cost of R&D on average, and I would like to
25 emphasize the average, recognizing failures, dry holes,

1 successes, when you average it all out, it works out to
2 about 800 million dollars per new chemical entity. This
3 is from a recent Tufts University study that was
4 published late last year I suppose.

5 The cost of failures or delays are devastating.
6 I won't get into specific examples, but the impact on
7 market value as a consequence of any failures or delays
8 are enormous.

9 By contrast, as was said, generics have to
10 establish bioequivalence. Which requires about one to
11 two years, and the costs, as I understand it, are up to
12 2 million dollars, and this is this is from a well known
13 expert in the field, Henry Grabowski of Duke University.

14 The importance of pharmaceutical innovations,
15 basically the idea is that economic studies have found
16 umpteen number of times that patent protection or
17 intellectual property rights are critical. It's kind of
18 well known, but the length of the market exclusivity is
19 more important in pharmaceuticals than in other high
20 tech industries, and contrary to popular misconception,
21 on average, and again on average, many marketed products
22 do not recover their R&D costs.

23 The source of this is a number of papers by
24 Henry Grabowski and John Vernon that have been
25 established, and I can provide the sources in detail

1 of due process and no forfeiture provisions for failing
2 to bring suit within 45 days. Normal statutes of
3 limitations should apply, no forfeiture of right to
4 trial by jury. There's legislation that effectively
5 deprives patentees of the right to have juries hear of
6 validity and infringement issues in ANDA cases, and
no private action for delisting from the Orange Book

1 of the Pharmaceutical Research and Manufacturers
2 Association of America, also known as PHARMAA.

3 MR. GLOVER: Good afternoon. I'm pleased to
4 participate in this panel on generic and branded
5 pharmaceuticals. I'm a physician and an attorney with
6 the law firm of Ropes and Gray, specializing in
7 representation of the research based industry on the
8 relationship between intellectual property and FDA
9 regulatory law.

10 My presentation will focus on innovation as an
11 essential driver of competition in the pharmaceutical
12 industry. Innovation is the primary source of
13 competition in the pharmaceutical industry. Innovation
14 produces new products that compete with products of
15 other research based companies in a given therapeutic
16 area.

17 To the extent that innovation does not occur,
18 research based companies and generics alike will have
19 fewer new products, and less competition will occur.
20 Both initial and sequential product innovation are
21 important features of the research and development
22 process in the pharmaceutical industry.

23 As you can imagine, innovation does not occur in
24 predictable consistent manner. Sometimes it occurs
25 quite serendipitously. In many cases the innovation

1 that first appears incremental can turn out to be
2 fundamental.

3 Innovation by brand name manufacturers has
4 provided new dosage formulations that permit changes
5 from intravenous to oral formulations, changes from four
6 times a day to once a day dosing and changes from
7 prescription to over the counter versions of products.

8 Moreover, product innovation results in a
9 variety of different drugs with the same therapeutic
10 class that have different clinical and side effect
11 profiles.

12 All of these innovations give physicians more
13 options to fit the drugs to the needs of the individual
14 patient. Even after the introduction of lower priced
15 generic copies of earlier versions of pioneer drugs, the
16 demand for improved variations, a test to the immediate
17 competitive significance of these innovations, as well
18 as to the related to the consumer benefits. In
19 addition, subsequent generic copying of these new
20 versions further expands their competitive impact.

21 Robust patent rights for initial and sequential
22 product development are needed to promote innovation and
23 related competition. These rights enable development of
24 government approved marketable drug products.

25 By providing research based manufacturers an

1 opportunity to benefit financially from the innovations
2 they develop, these rights also provide the necessary
3 incentive to promote further investment to support the
4 research, development and refinement needed to discover
5 future treatments and cures to protect the public.

6 The full range of patent protection is critical
7 to achieving the full benefits of innovation. While
8 patents are significant to innovators in most
9 industries, they're absolutely crucial to the
10 pharmaceutical industry. Without current levels of
11 intellectual property protection, there would be no
12 significant pharmaceutical industry, at least not in its
13 current form, and neither would there be a significant
14 generic industry because fewer drugs would be developed
15 for generic companies to copy.

16 Effective enforcement of these patent rights is
17 essential. Although the Hatch-Waxman Act prevents a
18 pioneer company from bringing a patent infringement
19 action, against a generic company during the generic
20 product development testing phase, the Act enables
21 effective enforcement of patent rights at the time a
22 generic applicant files its application.

23 By providing up to a 30-month stay on FDA's
24 approval of a generic copy of a patented product, the
25 Hatch-Waxman Act enables patent owners to have a limited

1 time to defend their intellectual property rights before
2 the generic product receives final approval from FDA.

3 Enormous investments are necessary to support
pharmaceutical innovation. It is aehtf8Wnsitcei,rt33

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1 dramatically reduced prices, as they have done at
2 increasingly high rates. Since the law's passage, the
3 generic industry's share in the prescription drug market
4 has jumped from less than 20 percent to almost 50
5 percent today.

6 An additional impact on pioneer generic
7 competition arises from reduced effective patent terms.
8 That is the time between FDA approval and patent
9 expiration. The full patent term in the United States
10 is 20 years from the date a patent application is
11 filed. Accordingly, innovators in most industries who
12 do not need regulatory approval before going to market
13 typically receive up to 18 and a half years of effective
14 patent life.

15 In contrast, pharmaceutical companies have a
16 strong inducement to apply for patents early in the
17 development process. As a result of this incentive and
18 of the lengthening development and FDA review times,
19 effective patent lives for pharmaceuticals have
20 declined.

21 The average period of effective patent life for
22 new medicines introduced in the early to mid 1990s for
23 patent term restoration was only about 10 to 12 years.
24 This trend also works to accelerate generic market
25 entry.

1 Thanks to the cycle of innovation supported by
2 effective intellectual property rights, the
3 pharmaceutical industry is characterized by substantial
 and increasing competition. As pharmaceutical companies

1 I want to take a moment to explain AARP's
2 interest in these issues. We are a nonprofit, non
3 partisan membership organization of more than 35 million
4 members aged 50 and older, and we work to foster the
5 health and economic security of individuals as they age,
6 including ensuring access to needed health care and
7 prescription drugs. To that end, AARP supports efforts
8 at the state and national levels to increase access to
9 more affordable drugs.

10 Now, when David invited me to participate, he
11 asked two questions. He said, Can you describe what the
12 general need and benefit to AARP's constituency will be
13 if we get quicker access to generics, and can you tell
14 us why AARP participated in litigation against the
15 industry?

16 So as to the first, I want to address it on two
17 levels. One would be the macro level of the general
18 numbers and statistics that drive our need to get
19 involved in the issue, and the second is on a micro
20 level of the individuals whose story we hear every day.

21 Access to prescription drug treatment is
22 particularly important to the older population which,
23 because of its chronic and serious health conditions,
24 has the highest rate of prescription drug use.

25 For example, Ms. McCluskey's organization,

1 Families USA, has reported that people over 65, although
2 only 13 percent of the population, account for 34
3 percent of all prescriptions dispensed and 42 cents of
4 every dollar expended on prescription drugs.

5 The rising demand for prescription drugs has
6 been, as we have heard, accompanied by a dramatic
7 increase in prescription drug costs, leading AARP to
8 support access to generic drugs, which has proven to be
9 a benefit to consumers by lowering the cost of
10 medication.

11 From 1993 to 1999, prescription drug spending
12 rose by 94 percent, over 2 and a half percent the
13 increase for total national health spending, which grew
14 by 36 percent over the same period.

15 A University of Maryland study predicts that the
16 increase in pharmaceutical spending will increase,
17 estimating the increase to be between 15 and 18 percent
18 per year from 1999 to 2004, more than doubling from 105
19 billion in 1999 to 212 billion in 2004, and the rise in
20 spending may be even greater than the Maryland study
21 estimated because we have information from the National
22 Institute for Health Care Management that spending of
23 prescriptions rose 18.8 percent in 2000, reaching the
24 total cost of 131.9 billion dollars last year, with an
25 average cost to fill a prescription being \$45.27.

1 Now, prescriptions account for approximately 19
2 percent of the average total out of pocket spending on
3 health care by Medicare beneficiaries. This does not
4 include home health care and long-term nursing home
5 costs by beneficiaries, and prescription drugs comprise
6 the largest category of Medicare beneficiaries health
7 care expenses after premium payments.

8 Medicare beneficiaries were predicted to spend
9 an average of \$480 out of pocket on prescription drugs
10 in 2000. Those who are in poor health or lack drug
11 insurance pay considerably more. Those who were in poor
12 health spent \$685. Those without drug coverage spent
13 \$715, and those who are severely limited in their
14 activities of daily living spend \$725. Research has
15 shown that uninsured, older and chronically ill people
16 do without drugs when cost become too great a factor.

17 A 2002 AARP study reveals that for Americans age
18 45 and older, more than one in five report that they do
19 not fill prescriptions prescribed by their doctor
20 because of the cost. The cost of the drug was the
21 primary reason people cited for not getting their
22 prescription filled. Of particular concern is that
23 the proportion of people who say that cost is the main
24 reason for not getting prescription filled is rising.

25 It's up from 13 percent in 1986 to 32 percent

1 this year. Without a doubt increasing access to lower
2 cost generics is one way to ensure that consumers will
3 fulfill the prescriptions their doctors have ordered.
4 Because generic drugs are priced much lower, they're a
5 source of substantial savings.

6 Recently, the rate of generic market penetration
7 has slowed and declined, and although Michael and two of
8 our panelists have discussed the rate of market
9 penetration at approximately 47 percent, it is clear
10 that since 1984, the rate of generic penetration is
11 declining.

12 Generic drugs market share, as a percentage of
13 total dollar sales, slipped from a high of 12.2 percent
14 in 1985 to 8.6 percent in 1998. As the FTC's Bureau of
15 Competition has pointed out, consumers save most on
16 prescription drugs when multiple generics enter the
17 market.

18 The average price of a generic drug declines as
19 the number of manufacturers of that drug increases, and
20 it makes sense that the sooner more companies offer the
21 same generic product, the greater the competition, and
22 the lower price consumers pay.

23 Now, a Brand I study in 2002, which was a study
24 supported by the generic industry, indicated that if
25 generic drugs were more widely available and utilized,

1 every person age 65 and older would save an average of
2 \$270 for prescription drugs, but these figures that I've
3 just rattled off are talking about the national macro
4 level, speaking to averages and the national problem.

5 When you hear the stories that our members call
6 us with, then you will begin to understand what savings
7 on the cost of prescription drugs means to them and what
8 faster access to lower cost drugs would do to improve
9 their lives.

10 AARP members call in and tell us about how much
11 they spend on prescription drugs and how their savings
12 keep going down. Many members call and say they can't
13 afford to take their medication, that they have to do
14 without or sacrifice in order to pay for their
15 prescriptions.

16 Some members call in tears explaining their
17 stories as they struggle to make ends meet, and many are
18 angry because of what they see as the increased cost of
19 prescription drugs greatly exceeding the cost of living
20 and what they see as the reasonable profit margin for

1 Maine and Michigan, which seek to provide discounts and
2 coverage for seniors for medically necessary drugs.

3 We are joined in litigation with consumers and
4 consumer groups affiliated with the Prescription Access
5 Litigation Group, an effort by community catalysts and
6 others to bring systemic change to prescription drug
7 competition. These cases, which we have joined, have
8 several things in common. First, they are cases of
9 national impact involving important drugs used by older
10 people.

11 They each allege that generics and name brand
12 manufacturers have reached settlement agreements
13 resulting in the delay of generic competition. One
14 member has told me that she spends 10 percent of her
15 income on Pador alone. Another woman says that the
16 Tamoxifen medication keeps her alive, but she can't
17 afford to pay for her other necessities of life.

18 As we've heard about and intuitively understand,
19 the amount of competition between drug manufacturers has
20 a direct correlation with the cost people pay for
21 medication, and the cost of medication has a direct
22 correlation with whether people can afford to purchase
23 them and get the benefit of these drugs.

24 Any delay in the availability of generic
25 prescription drugs means that consumers' access to life

1 saving and health enhancing medications is being
2 diminished.

3 Thank you.

4 (Applause.)

5 MR. KADES: Thank you, and our next speaker is
6 Amanda McCluskey, who is the Director of Health Policy
7 of Families First, a nonprofit, non partisan consumer
8 advocacy organization.

9 MS. MCCLUSKEY: Thank you. It's actually
10 Families USA.

11 MR. KADES: I'm sorry.

12 MS. MCCLUSKEY: That's okay. I believe there is
13 an organization out there called Families First, but
14 that is not us.

15 Thank you very much for the invitation to be
16 here. I'm delighted to be here and participate in this
17 discussion on an issue that's of such great importance
18 to so many Americans.

19 I would like to focus on three different areas
20 related to the questions outlined in the agenda. First,
21 I would like to look a little bit at the market from the
22 perspective of the consumer, particularly that consumer
23 that doesn't have prescription drug coverage and is
24 paying the full price for the prescription when they go
25 to the pharmacy counter.

1 while the rate of inflation during the same period was
2 2.7 percent. The story's the same if you look at the
3 price increases over five years as well. Over the
4 five-year period from January '97 to January 2002,
5 prices rose on average 27.6 percent or more than two
6 times the rate of inflation.

7 Among the drugs on this list of 50, ten are
8 generics, and 40 are brand name. In the last year,
9 prices for the generics most frequently used by seniors
10 increased by 1.8 percent, a rate less than the rate of
11 inflation. During this same period, prices for the 40
12 brand name drugs most commonly used by seniors increased
13 an average of 8.1 percent.

14 In addition, the generics not only rose slower,
15 but their prices are significantly less expensive. The
16 average of the 40 brand name drugs, the average price
17 was over 1,100 dollars per year for annual treatment
18 using these medications compared to 375 dollars of an
19 average for the generics.

20 Numerous studies have conducted head to head
21 comparisons of brand to generic drugs and show
22 significant savings for brands and generics within the
23 same category. Clearly, competition from generic drugs
24 offers seniors significant savings off of the brand name
25 price and generics are increasingly -- particularly as

1 that manufacture these 50 most commonly prescribed
2 drugs, and there are nine companies that are based in
3 the U.S. and that are publicly held and therefore
4 obligated to file with the SEC.

5 So we looked at those nine companies, and all of
6 those nine companies reported a profit in the last year
7 based on their SEC filings. Six of the nine companies,
8 and the six include Merck, Pfizer, Bristol Myers Squibb,
9 Wyeth, Lilly and Schering-Plough, had profits exceeding
10 their spending on R&D, and on average the nine companies
11 reported profits of 18 percent of total revenues, but
12 only 11 percent of total revenues was allocated to R&D.

13 We also wanted to look at other areas of
14 spending where we felt maybe direction was being
15 diverted from R&D and taking potentially money away from
16 that and a problem for why we weren't seeing any
17 interest in lowering prices or moderating prices.

18 So we also looked at spending on marketing
19 advertising and administration, and all nine companies
20 spent considerably more on marketing advertising and
21 administration than they spent on R&D.

22 Now, I don't want to go into this in great
23 detail because that's the conversation for the next
24 panel, but I did want to mention it is in the report.
25 The report is on the web site, again at Familiesusa.org.

1 So I want to close this off by saying that while
 2 I think it was Mr. Glover, Dr. Glover, who mentioned
 3 that this is a very risky industry and that drives a lot
 4 of what the industry does. At the same time, this is
 5 also a very profitable industry. Fortune 500 has ranked
 6 this industry the most profitable for the last ten
 7 years, and it's the most profitable by a large margin.

8 In fact, in the last year alone, the average
 9 profit margin for a Fortune 500 company was a little bit
 10 over 3 percent compared to around 18 percent for the
 11 pharmaceutical companies.

12 I want to move on to the specific questions
 13 about the loopholes. You can imagine as an organization
 14 that advocates on behalf of consumers, seeing these high
 15 and rapidly rising prices, seeing the difficulty that
 16 individuals have accessing generics, and this is
 17 particularly frustrating.

18 So Families USA is very supportive of efforts to
 19 close the loopholes in Hatch-Waxman. In particular, we
 20 believe efforts to limit brand name manufacturers to one

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1 the Orange Book in a timely fashion. We also believe
2 it's important to require both brand name and generic
3 companies to report agreements and agreements that they
4 have made about marketing of generic drugs and that
5 these areas need to be aggressively monitored to ensure
6 that the 180-day exclusivity for the first generic isn't
7 parked, to use the FTC's language.

8 Once the patent exclusivity is expired, every
9 effort should be made to get the generics to market as
10 quickly as possible. These delays have tremendous
11 financial implications for consumers.

12 Finally, I want to comment on one other area,

1 and I have been thinking about this a fair amount lately
2 and have sort of likened it to me-too drugs manufactured
3 by the same manufacturer as the original drug.

4 I think Claritin and Clarinex and Prilosec and
5 Nexium sort of give it away in their names to some
6 extent, but I think they're two great examples where the
7 manufacturer has gone to great lengths to make fairly
8 modest modifications in the drug to the extent that it's
9 unclear what the added value is for the patient and, at
10 the same time, have successfully protected the patent
11 and the exclusivity of the drug that they've initially
12 introduced.

13 So I just raise that. I know part of this
14 hearing was to sort of raise those other areas and look
15 at the FTC study, and I raise that as one other
16 possibility and one other area that I think is worth
17 looking at.

18 I just want to close by saying that we do value
19 the innovation and the innovative work of pharmaceutical
20 companies, but I think it's important to point out --
21 and I guess before I go there, I want to say not only do
22 we value it, we believe it should be rewarded, and
23 patent exclusivity is certainly one way to do that, but
24 we believe that we should be rewarding true innovation,
25 not simply modifications to an existing drug or me-too

1 drugs, but really true breakthroughs that offer real
2 advances in the treatment of care for individuals.

3 Thank you.

4 (Applause.)

5 MR. KADES: Thank you. Our next speaker is
6 David Reiffen, who is a staff economist in the Office of
7 Economic Policy at the Department of Treasury. He is
8 formerly a staff economist at the Federal Trade
9 Commission, and he's authored a study on the generic
10 drug industry or coauthored a study.

11 MR. REIFFEN: Thank you. I would like to thank
12 the FTC for inviting me today, and as was noted, I work
13 at the Treasury Department, and I have to give the usual
14 disclaimer that whatever I say today is my opinion and
15 not that of the Treasury Department.

16 As several earlier speakers discussed, recent
17 FTC enforcement actions have focused on certain
18 behaviors by innovator drug companies with respect to
19 generic firms, specifically as alleged, that innovator
20 firms colluded with generic firms to delay entry. For
21 example, in several cases the innovator and the initial
22 generic agreed to delay the introduction of the generic
23 product, typically in exchange for a payment by the
24 innovator, and that was discussed at some length today.

25 This is particularly important because certain

1 to obtain any additional FDA approval. It can simply
2 bring its product to market even before the patent
3 expires and certainly as soon as the patent expires, so
4 in combination, by introducing its generic product
5 before any independent generic firm can get FDA
6 approval, the innovator firm can take away a lot of the
7 profits associated with entering as a generic producing
8 drug.

9 That, in turn, can have a fairly substantial
10 effect on the number of entrants, so that was kind of
11 the hypothesis that we came up with, and in doing our
12 research for the study, we actually came across a quote
13 by a fellow named Morton Katz, who was then Chairman of
14 the National Association of Pharmaceutical
15 Manufacturers, which was very much in the spirit of what
16 we were talking about. So he's basically saying the
17 same thing, that the innovator comes in first. It will
18 be very difficult for any generic to make any money, an
19 independent generic.

20 So what we were doing in the study was to try to
21 estimate the magnitude of this effect, and so that comes
22 down to two questions. First, how big are the profits
23 that the first approved generic firm can expect to get
24 as a percentage of all the profits that can be made
25 producing a generic drug?

1 It turns out for the typical drug in our sample,
2 we estimate that a little more than half of the profits
3 go to the first entrant.

4 Then the second question is: What's the effect
5 of the number of entrants of removing this profit from
6 that available to the generic producer, so if a lot of
7 the profits from entering decline, they decline by the
8 amount we said, how many fewer generics will apply?

9 So what we do is we estimate a number of
10 structure relationships, which basically describe
11 competition within the generic sector, not competition
12 between generics and branded but from within, to answer
13 these questions, and they describe how competition
14 develops among the producers of specific kind of drugs.

15 As it turns out, although we developed those
16 estimates for the specific goal, that you can answer a
17 variety of policy questions with these same kind of
18 estimates.

19 So I'm going to turn first to the specific
20 question of what happens when these branded firms bring
21 out their generic firms, the innovator brings out his
22 generic product.

23 It turns out the size of the effect depends on
24 the sales volume of the drug, so if you have a drug that
25 had relatively small sales before patent expiration, the

1 the drug before a patent expiration.

2 For the large volume drugs in our sample, the
3 effect is much smaller. As you can see here the
4 difference between the two lines is much smaller. On
5 average over the three years, it seems like maybe it's
6 only 5 percent or something, maybe less, and the reason
7 is for a typical large drug, you might have a dozen
8 independent generic firms applying in the base case.

9 So if you have a reduction of three in the
10 number of generic entrants, they still have nine, and
11 moving from 12 to nine has a much smaller affect on
12 price than moving from five to two, and we're estimating
13 that, but that's part of what we're doing here.

14 So as I said, we estimated a bunch of structural
15 equations, and all these equations are describing in
16 what is going on in the industry, and none of them are
17 interesting in and of themselves, except perhaps the
18 relationship between the price of the generic drug and
19 the number of generic competitors, and that relationship
20 has been estimated elsewhere, but we were interested in
21 a specific aspect of it.

22 What we wanted to know is, we know generally the
23 more competitors there are the lower the price will be,
24 but we were interested in the question of when does that
25 effect go away.

1 As we say we think a second firm will always
2 lower -- having two firms will always introduce a lower
3 price than having one, but will seven have an effect on
4 price, seven rather than six have an effect?

5 So we estimated this relationship in a way that
6 will allow us to answer that question, and what we find
7 is somewhat surprising to us. The effect of additional
8 generic competition seems to persist, even as you move
9 out to six and seven firms.

10 Certainly it starts to flatten out. At about
11 ten, you get to about as low a price as you can, as
12 you're going to get, which is why the early result that
13 in large markets moving from twelve to nine doesn't have
14 much of an effect, but moving from five to two, you can
15 see what happens has a very big effect on price.

16 Now, I should give a few caveats here. We
17 estimated this in a number of different ways with
18 different measures of price. They don't all look
19 exactly the same, but the general picture is kind of
20 similar which gives us some reassurance, but I wouldn't
21 swear by these values. So that was what we did in
22 analyzing this previous practice.

23 If you look at the paper, you'll see we
24 discussed some other applications of these same kinds of
25 estimates, and the message that comes out of the paper

1 often seems there's very little we can agree on. We
2 haven't even been able to agree on the name of the
3 statute. Is it Hatch Waxman or Waxman Hatch?

4 As a former Waxman staffer, I call it
5 Hatch-Waxman, and I understand some of the Hatch
6 staffers have agreed to put Mr. Waxman's name first.

7 One thing I think there is general agreement on
8 is that the report by the Federal Trade Commission is
9 really very helpful. It provides a lot of information
10 that many of us have tried to get for quite awhile, but
11 have been unable to get. It puts it together very well,
12 and while I guess we all draw our own conclusions from
13 the report, I don't think there's any disagreement that
14 this is going to be very valuable as we consider these
15 issues and particularly as Congress considers the issue
16 this year and probably next year as well.

17 We're also not arguing about the value of patent
18 rights. I don't think anybody is suggesting that
19 patents aren't very important as an incentive to
20 pharmaceutical research. Nobody's contesting that there
21 used to be a 17 year patent. Now it's a 20 year
22 patent. There's a five year patent extension granted in
23 1984. There's a six month pediatric extension.

24 None of this debate is really about those patent
25 rights. The issue instead is: What happens after the

1 patent expires? What happens if the generic
2 successfully challenges a patent and is able to show
3 that it's invalid? And these turn out to be very, very
4 important issues because, as everyone in this room
5 knows, generic drugs have saved tens of billions of
6 dollars since 1984, and as I think most people would
7 acknowledge, there's potential for them to save much
8 more in terms of prescription drug costs.

9 I'm going to cover three or four of the issues
10 that seem to be key and just discuss a little bit about
11 what's at stake. The first one that you keep hearing
12 about is the so-called 30-month stay.

13 In any other industry, if a company such as a
14 generic company wanted to challenge a patent, it would
15 infringe on the patent. It would find itself in
16 litigation, and it would generally have the choice of
17 whether to go ahead and sell its product during the
18 litigation. Now, selling the product can be a very
19 risky course because if you lose, then you can pay
20 treble damages, and in this industry you literally
21 often would be betting your company.

22 So as the FTC report recognizes, even when
23 there's no stay of FDA approval, the generic companies
24 generally do not start marketing their product during
25 litigation, but there's one situation where you can

1 imagine a generic company would want to market its
2 product, and that's where it makes the assessment that
3 this is a very, very weak patent, highly unlikely to be
4 upheld. I think as a public policy matter, you want the
5 generic to be able to market its product in that case.

6 The 1984 Hatch-Waxman Act basically tells FDA
7 that once the generic files its application and says
8 it's going to challenge the patent, FDA can't approve
9 the generic drug for 30 months, and the Federal Trade
10 Commission report says that one 30-month stay is okay,
11 and the reason is that it takes 24 or 25 months
12 typically for FDA to approve the application, so there's
13 not much impact of that 30-month stay.

14 The original Senate legislation would have
15 eliminated the 30-month stay, and I think as you'll see,
16 that is the far simpler way to deal with this. This
17 state creates all kinds of complications. I guess I
18 would say in response to the point made in the report,
19 if the average time is 24 or 25 months, there are

1 30-month stay, appears to be very weak, but the issue
2 that's grabbed everybody's attention is something really
3 of more recent vintage. No one ever imagined in 1984 where
4 the first 30-month stay is about to expire, and so the
5 brand comes in and somehow manages to get a second
6 patent issued from the patent office, files it with FDA
7 in the so-called Orange Book and gets another 30-month
8 stay.

9 Under the law, as FDA has interpreted it,
10 allowed it to be implemented, there could be a third, a
11 fourth, a fifth, and in one case there actually have
12 been quite a number of 30-month stays, and almost
13 everybody who's looked at this is troubled by it.

14 The Commission was certainly troubled by it.
15 The legislation to pass the Senate would eliminate that
16 second 30-month stay and say there could only be one. I
17 don't know anybody who will seriously argue that the
18 1984 Act contemplated more than one.

19 That leads us to the Orange Book. The
20 significance of the Orange Book is that you get your
21 30-month stay only if you list your drug in the Orange
22 Book, so it becomes very important whether the patent is
23 actually listed in the Orange Book or not.

24 If we eliminated the 30-month stay, we could save
25 everybody trouble about arguing about the rules of the

1 Orange Book because they wouldn't matter so much, but if
2 we're going to have 30-month stays, then whether the
3 patent can go in the Orange Book or not matters.

4 Now, it's only supposed to go in the Orange Book
5 obviously if the patent claims the drug, if the patent
6 is tied to the drug, but the rules, as FDA have
7 implemented, basically are if the company wants to put
8 the patent in the Orange Book and certify that it's
9 valid, then the FDA treats its job as ministerial. As
10 Jarilyn said, it says, Do you really mean it, but if the
11 company certifies it again, the drug is in the Orange
12 Book.

13 The courts haven't been any more help because
14 they've said that the generics can't challenge the
15 Orange Book listing, so even if you have the best case
16 in the world, there was one case where the FDA had
17 essentially said that the drug did not match the
18 patent. It had gone ahead and listed it in the Orange
19 Book, and the courts said you can't challenge it.

20 Now, the legislation would do what to me seems
21 like a pretty small thing, which is to allow a generic
22 company that wants to challenge this Orange Book listing
23 to do so, not to have to do all this massive patent
24 litigation, but to simply say, Look, that patent doesn't
25 match the drug, I'll argue about its validity somewhere

1 else.

2 This has been, like everything else, very, very
3 controversial, and it's going to apparently be some
4 Bonanza for trial lawyers according to those who argue
5 against it, but the bottom line here I think is the
6 Commission said that where there have been patent
7 challenges, the generics have prevailed 73 percent of
8 the time.

9 So we're talking about real issues here. We're
10 talking about creating a situation where drugs can come
11 on the market long before the patent expires, if the
12 patent is invalid, and creating a real structure that
13 allows that to happen.

14 One provision in the law that's designed to
15 encourage this is the so called 180-day stay, and
16 basically what it says is the first generic to break a
17 patent gets a reward. It gets to be the only generic on
18 the market for 180-day days. The FTC study I think
19 supports this as an incentive. It suggests some
20 modifications, but I think they're minor enough that
21 they really don't merit discussing here.

22 Where the issue has really become interesting is
23 in these settlements, which the Commission says has
24 sometimes had the effect of blocking other generics. I
25 want to just say two things about that. One is whatever

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1 the only one to advertise that use.

2 One of the brand name companies had gotten a six
3 month extension for pediatric exclusivity, and one of
4 their lawyers thought of the bright idea: Well, let's
5 try to convert that to three and a half years; we should
6 get three years for our entire drug because nobody else
7 can put a pediatric claim on its label.

8 Congress addressed that in legislation last
9 summer, but they addressed it only for pediatric
10 populations. Undoubtedly, someone will try this for a
11 label having to do with some other type of population
12 because the pharma companies were very resistant to sort
13 of a broad fix of this issue.

14 Third issue is biologics. The '84 Act really
15 deals with chemical drugs, but today and in the future,
16 there will be increasing drugs made from living
17 substances, which are called biologics. There isn't a
18 generic system for them in place. Much hard thought has
19 to be given in the future to how you create a system to
20 allow pharmaceutically equivalent biologics. Otherwise
21 the patents on those drugs could be almost infinite.

22 In terms of the Commission's role, I assume it
23 will continue to play the role it has. I don't know
24 that the main issues are going to be so much antitrust
25 issues or the kinds of issues that the Commission

1 typically looks at, as they're going to be competitive
2 issues, and I think for the foreseeable future, the main
3 forum for those is going to actually be Congress.

4 In conclusion, the '84 Act was enacted because
5 at that time there were two imbalances in the
6 marketplace. The first is Congress concluded that the
7 brand name companies were losing too much patent time
8 due to FDA requirements and FDA approval, so upfront
9 there was too much patent time being lost, and Congress
10 gave a five year patent extension.

11 It also said the brand name companies were
12 gaining too much patent time at the back end. In other
13 words, it was unhappy that there were was such a lag
14 between the time the patent expired and the time the
15 generic drugs could come on the market, so to address
16 that, it created the generic drug program at FDA and the
17 whole ANDA process.

18 The whole theory of that program was give the
19 brand companies extra patent time, but the day the
20 patent expires, position the generics to come on the
21 market.

22 Today, there are new imbalances arising that are
23 creating delays in the times generics can come on the
24 market, and while the statute has been a great success
25 story as the report recognizes, there is need to make

1 more adjustments.

2 Thank you very much.

3 (Applause.)

4 MR. KADES: Thank you. Well, I think we've
5 pretty much heard from representatives of the major
6 participants in the pharmaceutical industry, either as
7 makers or buyers, and we've heard the representatives'
8 views.

9 What I would like to start out with is to maybe
10 try to turn the tables on the speakers a little bit and
11 discuss the issues that are not the ones that other
12 speakers have raised, so, for example, obviously the
13 representatives from PHARMAA and from Johnson & Johnson
14 talk about innovation. The representatives from the
15 consumer groups talk about access and cost.

16 Maybe I thought it might be worthwhile to ask
17 them each to respond to the issues that were raised by
18 each other, and I thought we would start by, I'll throw
19 this out to either one of the two representatives from
20 consumer groups, which is from your perspective, what
21 are the benefits of innovation in the pharmaceutical
22 market, and how is it that we should weigh those
23 benefits in making either policy decisions or
24 enforcement decisions in antitrust actions?

25 MS. LOCK: I'll jump in. Of course innovation

1 is -- as Bill pointed out, there's certain agreement
2 amongst manufacturers and consumer groups that
3 innovation is vitally important, and we support those
4 protections. The balance has to become, and
5 Hatch-Waxman certainly tried to strike this balance
6 between allowing competition and respecting those
7 rights.

8 From our perspective at AARP, we see the
9 overwhelming costs being continually driven up, and
10 there's got to be an examination as Families has done in
11 I think in some of their studies, maybe Amanda would
12 like to address this, between the balance between
13 profits and reasonable expectations of profits and when
14 the prices become so out of reach that most people can't
15 afford them.

16 MS. MCCLUSKEY: I'm happy to do that. I think
17 obviously I agree with Sarah, and I think I made it
18 pretty clear that we value innovation, and I think part
19 of it is how you define innovation, but I think the
20 trick here is balancing the notion of rewarding this
21 innovation.

22 I think a 20 year patent puts a pretty high
price, is a lot of 2t.3Iauea pretty high7

1 think there are loopholes in the existing laws, and I
2 think the companies have been very clever in maximizing
3 those to their advantage.

4 It goes directly to the point about profits, and
5 I think we are not here, I'm not here to say that the
6 companies are too profitable or what the right profit
7 margin is, but it's hard for me to deal with issues
8 around prices for people who can't afford drugs and to
9 hear companies say they can't absorb any reduction in
10 price, that they need more time, more maximizing of
11 their profits, of their exclusivity on the market when
12 people can't afford the product.

13 As far as I'm concerned, if people can't afford
14 the product, then the innovation doesn't exist for them,
15 and so I think there's a very delicate balance there,
16 but I think what we've seen in the work that the FTC has
17 done, we have done a number of our own, we have done a
18 series of work ourselves, again it's on our web site.
19 You're welcome to go and get that, if you want to give
20 me a card here, I'm happy to send it to you, looking at
21 where the companies have potentially used these
22 loopholes to go too far.

23 What that really means is people aren't getting
24 access to these innovations, so what does it matter? If
25 they don't exist, they might as well not exist if people

1 can't afford them, so I think it's really important to
2 say we're not saying they shouldn't be profitable.
3 We're not saying that we don't believe innovation should
4 be rewarded, but that's the point of the current patent
5 system.

6 That's why we give the companies a 20 year
7 patent, and we're talking about beyond that. I think
8 what Bill pointed out made a really good point. The
9 issue is what happens once the initial patent expires,
10 and that really is the question, and I think I can very
11 clearly say that Families USA feels that's enough, that
12 these companies are making billions of dollars a year on
13 these drugs.

14 I've got numbers. Lipitor, the manufacturers of
15 Lipitor made more than 6 billion dollars on that drug
16 just last year.

17 MS. LOCK: I would just like to emphasize that
18 when the money and the profits and costs are so
19 incredibly extreme, it becomes a good business decision
20 to make settlements and make million dollar settlements
21 to your would be competitors not to compete. That's
22 when there's a real problem in the system.

23 MR. KADES: I would like to give a chance to
24 either of the members from the branded pharmaceutical to
25 respond to that and perhaps add these two additional

1 ideas to the mix, which are, one, is it conceivable that
2 a system could put too much emphasis on innovation, and
3 secondly, some of the facts and statistics that were
4 raised by Ms. Lock and Ms. McCluskey such as the fact
5 that one in five elderly are not filling a prescription
6 due to costs, are those facts relevant to determining
7 whether the system is providing enough, too much or too
8 little incentive for innovation?

9 MR. GLOVER: Both of the statistics that were
10 raised as well as the comments that were recently made
11 as well as the statements made by Ms. McCluskey and Ms.
12 Lock when they first made their statements principally
13 addressed issues concerning access to medical care, and
14 PHARMAA, as well as these organizations, support a
15 prescription drug benefit.

16 That is, in fact, what they said they were
17 talking, and that is, in fact, what the principal issue
18 is. We do not believe that the issue of innovation is
19 inconsistent with access. We believe that it's very
20 important that the patients they described, the
21 constituency that they represent, continue to have both
22 access as well as the benefits that will come from new
developments by benefnRtTD rTD (snct, what they o m6cp 7hee fTj -

1 have in the past and have the benefit of reducing
2 overall health care cost because it allows the patients
3 to, for example, stay out of hospitals or to stay out of
4 higher cost types of medical care, so we think both of
5 those are important.

6 With respect to the question of: Is it possible
7 to have too much emphasis on innovation? As I said, I do
8 not believe that this is a challenge or a contest
9 between innovation and anything else that we're trying
10 to achieve. Clearly, where you have, as a general
11 matter, a view that you're competing between incentives
12 for innovation versus incentives to allow generics to go
13 on the market, that is fine.

14 I do not think, as they say, that we're truly
15 talking about what happens after the patent expires, but
16 because the language that we're using today is not very
17 precise, what the debate truly is, is whether what we
18 view as genuine innovation that is respected in the
19 marketplace, that physicians like, that benefit patient
20 care, is viewed by others as being innovation of the
21 type that needs to be protected, and whether what we are
22 doing in terms of an industry is what other people will
23 respect as being important.

24 We do not believe that we are always clairvoyant
25 enough to know whether the innovations that we make are

1 indeed overwhelmingly important to the public health or
2 they are incremental innovations. We simply don't
3 know. We're not that good at predicting, and similarly,
4 I don't think other organizations can look at what we do
5 and say: Some of that is good innovation and some of
6 that is worthless innovation.

7 MR. KADES: Let me turn to maybe a more specific
8 topic. One of the proposed reforms that has been
9 discussed here today deals with the 30-month stay, and
10 Mr. Schultz discussed his view that he did not think
11 that anyone envisioned multiple 30-month stays back in
12 1984 when Hatch-Waxman or Waxman Hatch was first passed.

13 I thought I would give the opportunity to
14 pharmaceutical manufacturers, and Bill can respond, as
15 to whether that was indeed envisioned and whether
16 getting rid of multiple 30-month stays is a good idea or
17 a bad idea.

18 MR. GLOVER: In 1984, I don't think anyone
19 contemplated any pharmaceutical industry of the degree
of sophistication and complexity that we have now, and I

1 this last January, stated in some circumstances
2 so-called multiple or stacked or what we've referred to
3 as nonconcurrent 30-month stays are appropriate in
4 certain circumstances.

5 We should also, however, take a look at why you
6 have these so-called nonconcurrent 30-month stays.
7 There is one view that says that this is the result of
8 the pharmaceutical companies getting more and more
9 patents on their products. And, indeed, the trends will
10 demonstrate that as we've gotten more sophisticated in
11 our research and development, that we do find aspects of
12 our products that are patentable, and often these
13 patents and innovations for the products occur, hit
14 several stages, and therefore you have multiple
15 patents.

16 As we also know, regardless of the number of
17 patents that exist on a product at the time an ANDA
18 applicant files its application, there's only going to
19 be a single 30-month period in which all the 30-month
20 stays run concurrently, so the real debate is not so
21 much why are there multiple patents on pharmaceutical
22 products, but why is it that some of these patents are
23 being issued by the patent office and subsequently
24 listed in the Orange Book after the ANDA applicant files
25 its application.

1 There are going to be two things that lead to
2 that. One is that, as always occurred, innovation for
3 the large pharmaceutical companies occurs on a step-wise
4 basis. There may be patents that you are filing for
5 throughout the development process up until and perhaps
6 even beyond when you first file your NDA or your NDA
7 gets approved.

8 Those patents will be issued by the patent
9 office in due course, and indeed some of those patents
10 will be issued by the patent office some years after the
11 drug first goes to market.

12 The second thing that is occurring, however, is
13 that contrary, as you may have seen from some of the
14 data in the FTC report that was presented here today,
15 there seemed to be a change in activity in 1998. One of
16 the reasons there was a change in activity in 1998 is
17 because there was a new interpretation of the law
18 relating to when generics were eligible for the 180-day
19 market exclusivity.

20 Prior to 1998 and from 1984 basically to 1998,
21 the interpretation was the generic had to be both first,
22 and they had to successfully prevail in a patent
23 infringement suit against the pioneer in order to get
24 the 180-day exclusivity. In 1998, this was thrown into
25 question, and eventually we have settled upon a role

1 approved.

2 It's on the market, and at some point a generic
3 company decides that the patent may be invalid so it
4 challenges the patent. That's then litigated for 30
5 months in District Court, Court of Appeals or whatever,
6 and as that 30 months is about to expire, lo and behold,
7 the pharmaceutical company finds another patent that it
8 lists on that drug that was patented years and years
9 ago.

10 Nobody is suggesting they shouldn't be able to
11 get that patent, that they shouldn't be able to modify
12 their product, but the question is: Should the generic
13 be able to match the old product with the old patent or
14 should this new patent be able to block it?

15 I want to emphasize, we are talking around the
16 edges now. We're not talking about fundamental change.
17 We're not talking about cutting down patent time. And I
18 think it's quite interesting that there's been only a
19 small number of companies really that have engaged in
20 these abuses.

21 There are plenty of brand name companies that
22 have been very innovative and very profitable without
23 this kind of maneuvering, and I suggest that that alone
24 is some evidence that there's something wrong here.

25 MR. KADES: Well, I think that concludes our

1 time for this panel. I want to thank you all for taking
2 time and giving us your thoughts, and we wish you the
3 best.

4 MR. HYMAN: We're going to continue. First let
5 me just mention there are additional copies of the
6 Federal Trade Commission Generic Drug Study outside, so
7 if you didn't pick one up earlier, they're now there.
8 They're at both the fourth and fifth floors. I'm not
9 sure about the third floor.

10 I would like to now introduce from the Food and
11 Drug Administration, Lesley Frank, to give us an
12 overview of direct to consumer advertising before we
13 have our last panel on that subject.

14 MS. FRANK: Thank you, and good afternoon to all
15 of you. I'm sorry to say the CD I brought in is not
16 working, so there's no PowerPoint. Sorry about that,
17 folks.

18 I'm going to try to give you an overview of the
19 direct to consumer promotion of prescription drugs. We
20 have FDA regulation for drug promotion and take
21 enforcement action to ensure that the FDA regulated
22 parties comply with the so-called promotion provisions
23 of the federal Food, Drug and Cosmetic Act.

24 I want to be clear when I talk about FDA
25 regulated parties, I'm talking about manufacturers,

1 packers, distributors, NDA holders, investigators even,
2 and anyone who works on behalf of those parties, and we
3 have essentially within FDA Center for Drug Evaluation

1 letter. Instead it's to provide information to all
2 regulated parties as to our enforcement activities and
3 rational so they can avoid the same kind of violations,
4 the concept many people believe is false.

5 If you see direct to consumer promotion of
6 prescription drug on television, and you get a brochure
7 or see an ad in Time Magazine, that this material has
8 been cleared by FDA. This is not true for the most
9 part. We do not pre clear the vast majority of all
10 promotional materials.

11 Therefore it's important to understand that our
12 enforcement actions are in essence taken after the
13 fact. That's because with the exception of drugs
14 approved under what's called Subpart H, you're
15 accelerated approval drugs on HIV drugs and those drugs
16 distributed through restricted access, they have a
17 requirement of submitting terms ahead time, but that's
18 more of a pre submission requirement we can review if we
19 have the time and generally we do.

20 Not all NDAs -- two copies of form 2253 get sent
21 to the agency. We get over 30,000 pieces a year. We
22 will review launch material when requested by the
23 company. This is not a requirement. There is no pre
24 clearance requirement.

25 We can only regulate that promotional material

1 that falls within the legal definition of labeling and
2 advertising, and FDA defines labels as any written
3 printed or graphic matter upon or accompanying the drug
4 product, and in contrast to what you have on a drug
5 bottle, you get your prescriptions, that's the label.

6 Labeling is a little more expansive, and to be
7 construed as a label, it need not physically accompany
8 your little bottle of medication. It need only
9 supplement, that is, explain it.

10 What I'm saying is a drug product can be shipped
11 from New Jersey to Florida, and a brochure about the
12 drug by the same manufacturer is shipped from Texas to
13 California, and that piece of labeling is deemed to
14 accompany the drug for our jurisdictional purposes.

15 Advertising, on the other hand, is not defined
16 in the statute. The Act does say that advertising
17 doesn't apply to anything that's been previously
18 determined to be labeling, and you go to the
19 regulations, and they give you have examples that
20 include advertisements in published journals, magazines,
21 periodicals, broadcast through media such as radio,
22 television, telephone communication systems.

23 Those aren't the limit but good examples.
24 Okay, why do we do this? Why do we regulate promotional
25 labeling and advertising? The fact is false, misleading

1 unbalanced, unsupported information may increase risk to
2 consumers. Consequently that false, misleading,
3 unbalanced information causes a drug to be misbranded in
4 violation of the Act.

5 Our job at DDMAC is to protect and guard against
6 false, misleading advertising, protect public health, by
7 our complements of enforcement and educational program.

8 Now, in order to be compliant with the Act,
9 promotional and labeling, advertising materials may
10 recommend or suggest drugs only for those uses contained
11 in the approved product labeling. That's the PI,
12 package inserts.

13 Claims made in promotion cannot be inconsistent
14 with that. They can't be -- promotional material can't
15 be false, lacking in balance, omit material facts or
16 otherwise be misleading.

17 Basically what the law calls for and what we
18 should see in an ideal world is the dissemination by FDA
19 regulated parties of truthful, informative labeling and

1 a significant risk to the consumer. Yes, they do also
2 provide the significant benefit, but this information
3 needs to be communicated.

4 When I talk about false or misleading, what am I
5 talking about? Well, promotional material can't state
6 or imply a prescription drug is safer or more effective
7 than shown by the clinical evidence. It can't state or
8 imply that it's more effective for a broader range of
9 populations, again demonstrated by the scientific
10 evidence.

11 Now, you have a general idea sort of what we do
12 and why we do it, and I want to turn specifically to DTC
13 promotion. In the early 1980s, it looked like DTC
14 promotion of prescription drugs was going to be the wave
15 of the future.

1 sufficient safeguards to protect consumers.

2 Up until the 1990s, what did you see?

3 Manufacturers were really trying to get the information
4 to the patient after the drug was prescribed through the
5 physicians, through the pharmacists, through health care
6 professionals in general. The material itself was
7 designed to be used after the prescription was
8 received.

9 There were also things called health seeking or
10 disease oriented promotion. Now, this tried to increase
11 the number of consumers going to their doctors, asking
12 about a particular problem. The ads disclosed that the
13 particular health condition or medical problem existed,
14 revealed that doctors have treatments for this
15 condition, and it urged the effect that consumers see
16 your doctor.

17 We saw reminder ads, the name of the drug.
18 Reminders ads are exempt from the agency's advertising
19 regulations because all they do or are supposed to do is
20 call attention to the fact that the drug exists.
21 They're not full prescription drug ads. They can have
22 things like the drug's name, dosage form, package type
23 price. Any mentions of drugs effectiveness or safety
24 triggers a balancing requirement of risk information,
25 brief summary, et cetera.

1 nature of broadcast media such as TV or radio, the
2 regulations actually do modify the requirements in the
3 case of a broadcast ad.

4 Yes, you have to have your indication. That's
5 your benefit, but they also have to reveal the major
6 risks of the prescription drug. Internally we call this
7 the major statement, and by regulation, it has to be in
8 either the audio or audio and visual portions of the
9 broadcast ad, and then -- oops, I've got the stop, and
10 can I just add?

11 MR. PAHL: Please finish off your remarks.

12 MS. FRANK: You've got benefit. You've got
13 risk. You can either scroll the brief summary which you
14 see on print ads, which no one is going to buy the time
15 for, I have to admit, and in a way that someone can
16 actually read it. In the alternative, the regulations
17 say you can make adequate provisions for disseminating
18 the PI.

19 And we put our heads together, tried to figure
20 out what did that mean. We talked to industry. We
21 talked internally, and we basically came up with a four
22 component approach, and we came up with a guidance. A
23 guidance just means it's not binding on us. It's not
24 binding on regulated parties. It's just our thinking.

25 Certainly we need a very good reason to deviate

1 from it, but we said, okay, you've got a multi faceted
2 audience, you have to address this audience, you need a
3 diverse approach, you've got people who are
4 technologically not sophisticated, people with privacy
5 interests. They don't want to leave their names. They
6 don't want to leave their addresses. They don't want
7 the material mailed to them. It's a matter of health,
8 they don't want people to know they're asking about this
9 drug.

10 So with all these concerns, okay, we have a
11 reference in the ad we see on T.V. to a toll-free
12 telephone number. A person could request a PI be mailed
13 or read over the phone. People don't want their phone
14 numbers picked up by some sort of caller ID at the other
15 end and registered so people don't do that.

16 Then reference the fact that health care
17 providers can provide more information, certainly we
18 want to encourage that. The listing of an Internet
19 URL. A lot of people have Internet. A lot of people
20 just like to go on and check. There are a lot of people
21 who don't have Internet access, don't want it and are
22 afraid to be identified with cookies or anything else.

23 That's why we also have reference in the ad to a
24 concurrently running print ad so a person in their own
25 private way can go to a place that they normally access,

1 whether it's a library grocery store, pick up a
2 magazine, open it, and there it is, and there's the risk
3 information.

4 Basically what this all assumes, however, is
5 that you've got truthful information, consumer friendly,
6 in context with -- you can't omit material facts. The
7 limitations have to be disclosed for use with diet and
8 exercise, only for use with med, again consumer friendly
9 language. The whole idea is that you're providing a
10 sufficient basis to enable the consumer to discuss the
11 prescription drug product with his or her health care
12 provider.

13 Now, just very briefly the type of enforcement
14 we do, we have entitled letters. They're typically less
15 severe violations of the Act. Warning letters, on the
16 other hand, they're more severe violations of the Act.
17 They're egregious, repetitive behaviors, violations that
18 could actually lead to enforcement actions right away if
19 not promptly corrected.

20 Additionally in the enforcement arena we have,
21 under certain circumstances, entered into consent
22 decrees with pharmaceutical companies to require
23 submission of promotional material before they went out
24 with it, not pre clearance, again pre submission
25 requirement.

1 None of those I would like to say were a DTC,
2 and finally seizure of the misbranded product is always
3 an option. It has not been used in recent memory in the
4 area of violative prescription drug promotion.

5 I would like to thank you for inviting me to
6 speak here today, and I would be happy to answer any
7 questions. That's it.

8 MR. PAHL: Thank you, Lesley.

9 (Applause.)

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1 jurisdiction over DTC advertising, Federal Trade
2 Commission also has jurisdiction over DTC advertising
3 although pursuant to a memo of understanding between the
4 two agencies, FDA has primary jurisdiction.

5 The other thing I would note is that in 1996,
6 when the FDA adopted its current approach to DTC
7 advertising, the FTC staff filed comment with the FDA
8 opining that the DTC approached being considered and
9 which is subsequently being adopted was likely to
10 increase consumer welfare.

11 Among other things, the FTC staff comment said
12 that such advertising was likely to provide timely
13 information regarding medical advances, remind consumers
14 about good health practices and supply information
15 needed by consumers to understand and evaluate their
16 physician's recommendations.

17 I guess the question our panel is going to
18 address here is whether DTC advertising has met these
19 high expectations, and I look forward to hearing from
20 all our panelists on that topic.

21 Without further ado, I think it's time to hear
22 from our distinguished panelists. Each of them will
23 have ten minutes to provide some opening remarks, after
24 which if there's any time left, I will pose some
25 questions about DTC advertising, and it's been a very

1 long hard day for everyone, so I hope we're going to try
2 to finish up at five o'clock as we're scheduled to do.

3 So without further ado, our first panelist
4 will be Rebecca Burkholder from the National Consumers
5 League.

6 MS. BURKHOLDER: Good afternoon. It's a
7 pleasure to be here today. The National Consumers
8 League is a national not-for-profit organization that
9 has represented consumers and workers since 1899, over a
10 hundred years, and the League has long been involved in

1 FTC posed, including: Is there evidence that DTC
2 advertising is harmful or beneficial to consumers; and
3 what consumer protection issues are raised by DTC? I'll
4 focus on the following, the sources of health
5 information, communication between health professional
6 and the patient/consumer, consumer response to DTC
7 promotion, are DTC affords effectively communicating
8 risks and benefits and prescription for reform of DTC
 promotion.

1 and going on down there.

2 The AHRQ survey further looked at the degree of
3 trust consumers place in the sources of information.
4 The results seemed to show that although consumers had
5 broad information seeking habits, in the end they trust
6 very few with their own health.

7 According to the AHRQ survey, consumers trust
8 the following sources a lot to provide accurate
9 information about prescription drugs. As you can see,
10 doctors are at the top of the list, pharmacists, and
11 then at the bottom the DTC ads 6 percent.

12 Prevention Magazine's 2000 survey of consumer
13 reaction to DTC ads reported similar skepticism for
14 everyone and everything, save a consumer's own physician
15 and pharmacist. That survey showed that only 5 percent
16 trusted print or broadcast ads of prescription drugs a
17 lot.

18 So in short, consumers seek and obtain
19 information from a variety of sources, but they are
20 skeptical of claims in DTC promotion and are most likely
21 to place the greatest trust in their own health care
22 professional.

23 Second, the impact of information on the patient
24 physician relationship. The National Consumers League
25 recently explored how consumers increased access to

1 health information is changing the doctor patient
2 relationship by conducting a series of focus groups with
3 patients and doctors this last year and this year.

4 Both doctors and patients acknowledged in the
5 groups that patients were taking on a greater role in
6 managing their health and that the patients actually
7 wanted to become a partner with their doctor, and what
8 happens to be driving consumer's interest and comfort in
9 this is increased access to information, especially the
10 Internet, which provides consumers with speed access to
11 huge quantities of information. While many doctors in
12 the focus groups welcome the informed and engaged
13 patient, other doctors found such patients threatening.

14 Patients also talked in the focus group about
15 doing their homework before a medical appointment. This
16 process includes reading magazines and tearing out
17 articles and advertisements about over the counter or
18 prescription drugs, containing online searches and
19 gathering information by word of mouth from friends,
20 family and co-workers.

21 Doctors discussed the impact of this
22 information. Doctors talked about feeling frustrated
23 when they walk into an exam room and see the patient
24 holding a stack of papers from various web sites and

1 magazine ads that may contradict his or her own
2 professional judgment, and when faced with all this
3 homework, physicians are often frustrated by the
4 credibility of that information.

5 Physicians were concerned that patients take
6 much of this information as scientific, regardless of
7 the source and whether there was any research or
8 evidence to support the findings, and most of the
9 culling of the good information from the bad occurs in
10 the exam room where time is already scarce.

11 Yet the solution is not to shut off this
12 river of information. Patients probably cannot
13 determine on their own whether the information gathered
14 is applicable to their condition, and every patient is
15 entitled to an informed conversation with his or her
16 physician.

17 The solution lies in facilitating an open,
18 unrushed exchange between the patient and the doctor,
19 not in abandoning the communication that prompted and
20 fielded the discussion in the first place.

21 Third, consumer response to DTC promotion. DTC
22 promotions are reaching consumers and prompting
23 discussion and information seeking behavior. 70 percent
24 of respondents to the Prevention survey stated that they
25 asked their doctors for more information as a result of

1 the DTC ad while 28 percent asked for the specific
2 prescription.

3 The Prevention survey also estimates that as a
4 direct consequence of DTC promotion, as many as 21
5 million Americans discussed a medical condition or
6 illness with their doctor that they had not discussed
7 before.

8 Similarly the FDA's 2002 patient survey on
9 direct to consumer advertising reported that as a result
10 of drug ads 18 percent of consumers talked to their
11 doctor about their own medical condition or disease,
12 something they had not done before. As you can see that
13 has dropped off in 1999 where there were 27 percent.
14 Overall, the data show that doctors are prescribing the
15 advertised medications when consumers ask for them.

16 The Kaiser survey reported that of the 30
17 percent who talked to their doctor about a medicine they
18 saw advertised, 44 percent gave the prescription asked
19 for. FDA's recent survey reported an even higher result
20 of the 23 percent of the consumers who saw an ad and
21 talked to their doctor. 69 percent of those who asked
22 for a specific brand received it.

23 It is difficult to draw conclusions about DTC
24 advertising based upon increased utilization alone.
25 More drugs are being prescribed for many reasons. Drug

1 promotion is one factor. In NCL's view, the appropriate
2 prescribing of medications results in a healthier, more
3 productive population. Increased utilization is
4 worrisome if it's due to unnecessarily, improperly
5 prescribed prescription drugs.

6 Ultimately the responsibility rests with the
7 physician to choose among treatment alternatives and
8 prescribe an appropriate medication, and DTC advertisers
9 bear the responsibility to present useful drug
10 information in a manner that is truthful, complete,
11 understandable and does not create unreasonable
12 expectation.

13 DTC advertisers have done much to educate and
14 inform consumer about how prescription drugs can improve
15 health. They have been much less successful in
16 communicating the risk.

17 Is DTC advertising effectively communicating
18 risk and benefit information? Under current FDA
19 regulations, prescription drug promotion must fairly
20 balance the positive information about safety and
21 effectiveness against the negative information about the
22 drug's side effects and contraindications.

23 Yet consumers are not taking away important
24 information from DTC advertising that otherwise
25 technically complies with all legal requirements. DTC

1 advertising is not communicating risk information
2 effectively, and even benefit information could be
3 conveyed more clearly.

4 The DTC ads do seem to raise awareness of
5 certain prescription drugs. Over two thirds of the
6 respondents to the League's '98 survey always or
7 sometimes increased their knowledge of medicine and also
8 increased their knowledge of disease, and the Kaiser
9 survey report concluded that the three drug ads shown to
10 consumers were effective in communicating very basic
11 information, the name of the drug and what it treats.

12 However, the Kaiser survey also found that
13 consumers did not gain much knowledge beyond that. Even
14 after seeing a DTC ad, 70 percent of consumers reported
15 that they knew little or nothing more about the health
16 condition for which the drug was indicated. 59 percent
17 knew little or knowing more about the medicine.

18 As for conveying important risk information, DTC
19 advertising is especially lacking. The Kaiser survey
20 report noted that FDA guidelines require that television
21 prescription drug ads include a major statement formerly
22 disclosing all the risks associated with the drug.

23 As the report states, just because the ads
24 included this information, it is not necessarily
25 successfully communicated to viewers, with the exception

1 of one of the side effects mentioned in one ad, about
2 half or more of the respondents could not correctly
3 identify the potential side effects after having just
4 views an ad.

5 For print ads the Prevention survey that over 50
6 percent thought print advertising did only a fair or
7 poor job of communicating serious warnings.

8 In addition the brief summary has failed to
9 communicate useful risk information to consumers.
10 Required to accompany all print advertisement, the brief
11 summary is frequently nothing more than a reprinting of
12 the warnings, indications, contraindications and side
13 effects from the drug product's full package labeling
14 which is written for health professionals.

15 It is dense, printed in minute type, highly
16 technical and contains every single side effect ever
17 potentially associated with the use of the drug. It is
18 typically neither legible nor comprehensible.

19 The FDA 2002 survey reported that among those
20 interested in a drug advertised in the print media,
21 that's those interested, 54 percent reported that they
22 read about half, little or known of the brief summary,
23 and 55 percent found the brief summary somewhat hard or
24 very hard to understand.

25 Lastly, I will discuss just a few alternative

1 models for disclosure of risk and benefit information in
2 DTC promotion that will better advance consumer welfare
3 and public health.

4 First of all new regulations. FDA must either
5 amend the old 21 CFR Section 202.1 or promulgate a new
6 regulation that specifically addresses DTC promotion.
7 This regulation was written to advise sponsors on how to
8 promote their drugs to the medical profession. The new
9 regulation specific to DTC advertising should
10 incorporate lay consumer comprehension into evaluative
11 criteria.

12 Reformat the brief summary, the brief summary
13 must be formatted to provide important risk and benefit
14 information, a consistent balance format and be written
15 in plain language a lay consumer will understand. The
16 summary should include important use and safety
17 information, identify who should and should not use the
18 product.

19 The brief summary should not include, as it must
20 now, every single risk in the full product labeling, but
21 emphasize the most serious and most frequent side
22 effects.

23 Third, standardize format for risk and
24 benefits. In NCL's view the format for presenting risk
25 and benefit information for prescription drugs should be

1 standardized as it was for over the counter drugs and
2 foods, and this way consumers can become familiar with
3 the single format and learn how to use it to obtain
4 important health information.

5 The drug facts and nutrition facts formats
6 provide excellent models for a standardized presentation
7 for important risk and usage information.

8 Lastly, include health professionals. DTC can
9 be a surprise intrusion into the physician patient
10 relationship. Thus drugs sponsors should include health
11 professionals in advertising campaigns so they're
12 prepared to address consumers inquiries and health
13 professionals should not be threatened by the empowered
14 and curious patient.

15 The patient inquiry is a request for a dialogue,
16 and the health care professional should respond with
17 information about the drug, its risk and benefits, about
18 generic availability and therapeutic alternatives.

19 So consumers have gleaned health care for a
20 variety of sources, but for all these rich and varied
21 sources, they continue to trust their health to medical
22 professionals.

23 Thank you.

24 (Applause.)

25 MR. PAHL: Thank you, Rebecca. Next we'll hear

1 from Dr. Jack Calfee who is a resident scholar at the
2 American Enterprise Institute.

3 MR. CALFEE: Thank you. I don't have a
4 PowerPoint, and it occurred to me maybe I could just
5 talk from here.

6 MR. PAHL: That would be fine.

7 MR. CALFEE: Minimize transaction costs, as it
8 were.

9 I provided outside, I'm sure most people missed
10 it, a brief one-pager outline my remarks. I'm going to
11 follow that. Essentially I want to make six points
12 about DTC advertising, and the first is strictly
13 background, probably a point with which everyone in this
14 room agrees which is consumers need to take more action
15 on their own behalf than they used to in connection with
16 health care, and specifically in connection with getting
17 drug therapies that can be a value to them.

18 I would point out this is not just a matter of
19 the growth of managed care and less time with the

1 not just in connection with arthritis but often in other
2 connections often, and the other one being the side
3 effects of cancer therapy. The side effects of
4 chemotherapy can be quite severe, and again there are
5 drugs that can help with that and again consumers are
6 often lacking in the information about these drugs that
7 could be of value to them.

8 Point number 3, advertising and promotion is a
9 demonstrated mechanism for overcoming the gap in
information between what the literature says and what

1 The FDA has conducted two consumer surveys.
2 Prevention Magazine has conducted at least three, with a
3 fourth now under design. There have been several other
4 surveys. All these surveys, the ones that I have in
5 mind, are large, representative surveys of consumers.
6 All of them are well designed. They're quite
7 informative, and they're surprisingly consistent across
8 the different surveys.

9 Point number 5, this evidence now permits us to
10 reach some kind of preliminary assessment of the costs
11 and benefits of DTC advertising. Let me focus first on
12 the potential harms from DTC ads. So far, the evidence
13 tells us that the harm from DTC ads is minimal. It may
14 have been very, very slight indeed, and this appears to
15 be true in connection with several specific items of
16 concern.

17 One is inappropriate prescribing. A second is
18 the possibility of deceptive advertising and its
19 effects. Third, the potential distortions in the
20 relationships between doctors and patients and finally
21 the impact of DTC advertising on prices.

22 I won't go through these in detail. In my
23 handout I did cite and provide a link for a paper that
24 goes through these items in probably more detail than
25 you would like to encounter.

1 previously expected , and you would expect to see
2 doctors prescribing these drugs more aggressively.

3 So far we haven't seen much of that, and that is
4 one reason why with all the debate about pharmaceutical
5 prices and pharmaceutical access, the main topic of
6 discussion right now at least in political terms is how
7 to assure access to these drugs rather than how to
8 curtail prescriptions that should not be written.

9 Also let me mention briefly on the question of
10 deceptive advertising, and here the point that I think
11 is worth making is that the FDA standards for deceptive
12 advertising are extremely stringent, far more stringent
13 than those in the FTC in the halls of this particular

1 their own standards is quite limited, and the effects,
2 if any, seem to be very, very small.

3 Finally, point number 6 in my brief list is what
4 the evidence tells us so far about the actual and
5 potential benefit of DTC advertising, and what we've
6 seen so far is those benefits seem to be quite varied
7 and they appear to be fairly substantial, at least at
8 this point. Advertising certainly increases consumer
9 and physician awareness of the potential benefits of
10 pharmaceuticals, in other words, it is helping to close
11 the information gap.

12 The advertising is prompting more discussions
13 between patients and doctors about drugs as one or two
14 speakers have already mentioned. There's considerable
15 evidence that something on the order of 20 percent of
16 the population, maybe a little bit more than that, has
17 been motivated by DTC advertising and talked to a doctor
18 about a condition they had never previously discussed.

19 If this were the only effect of DTC advertising,
20 that would be a very large and very important benefit
21 when you consider the kinds of drugs that are being
22 advertised for osteoporosis, depression, elevated
23 cholesterol, et cetera, conditions that people often
24 don't discuss with their doctors, and if as a result of
25 the DTC advertising they are discussing these

1 conditions, the benefits of doing so can be quite
2 substantial.

3 DTC advertising is increasing consumer awareness
4 of both risks and benefits of drugs. It seems to be
5 making people feel more comfortable about the drugs they
6 have been prescribed. They seem to be, if anything,
7 more aware than they have ever been that drugs are
8 inherently dangerous, that they should be treated with
9 caution but they can also be beneficial and that, they,
10 along with their doctor, should be balancing these
11 things.

12 The evidence suggests that DTC ads are probably
13 increasing compliance with drug therapy. If this again
14 is the only thing DTC advertising were to do, the
15 benefit can be very, very substantial given that
16 noncompliance with drug therapy is one of the most
17 stubborn and difficult problems that the medical
18 profession has encountered, and they have not come close
19 to solving the problem of noncompliance with drug
20 therapy.

21 I think it's possible that five years from now,
22 ten years from now when we look back at the DTC
23 advertising, a lot of us may think that the effects of
24 DTC on compliance may be the single most important
25 effect and the most important benefit of DTC

1 advertising.

2 Oddly enough DTC advertising has increased
3 consumer awareness of non drug therapy for important
4 medical conditions, and if you think about it, the
5 reasons are pretty obvious. If you advertise a drug to
6 treat obesity or cholesterol or other conditions,
7 several other conditions, the first thing that will
8 happen if your ad causes someone to talk to the doctor,
9 that person will receive lifestyle advice, and the
10 survey, not just consumer surveys but surveys of doctors
11 show that is exactly what happens.

12 When people go in to see their physician about
13 diabetes, for example, the first advice they get is
14 lifestyle advices, and it's pretty far down the road
15 before they start getting any kind of drug therapy.

16 What this means if one looks at the attention to
17 non drug therapy and the effects on compliance, that DTC
18 advertising may be having important positive
19 externalities or positive spill over benefits for the
20 market, and by that I mean benefits that go to consumers
21 but are not captured by the brands doing the
22 advertising.

23 Finally, DTC advertising substantially
24 reinforces industry standards to develop new drugs and
25 to research new uses of existing drugs. Thank you.

1 MR. PAHL: Thank you, Jack.

2 (Applause.)

3 MR. PAHL: Our next panelist is Dr. Steven
4 Findlay. He's the director of research for the National
5 Institute of Health Care Research and Educational
6 Foundation.

7 MR. FINDLAY: Good afternoon. We're pleased to
8 have the opportunity to participate today. I would also
9 like to make six points. Jack and I didn't coordinate
10 on that, but it just seems a good round and short
11 number, and I'll try to make my remarks as brief as
12 possible to get to the discussion.

13 I would like to make six points and then four
14 specific recommendations pursuant to the questions posed
15 to this panel by the FTC staff that did a great job in
16 the last two days of bringing us all together. I've
17 been through most of the last two days, and it's been
18 terrific.

19 First, to state the obvious, DTC ads are very
20 visible. That visibility has focused media attention on
21 the ads, and both of these, the visibility and media
22 attention, has tended to obscure other forces
23 contributing to the increase in prescription drug use
24 and spending.

25 The fact is DTC drug ads are but one factor in

1 the rapid rise in prescription drug spending since 1995,
2 '96, '97. Earlier today we heard about some of those
3 other forces, but just to tick them off, increased
4 insurance coverage of drugs, more drugs being approved,
5 an increase in the diagnosis of many chronic conditions
6 that afflict millions of people, and an increase in the
7 markets to physicians and the free samples particularly
8 provided to physicians.

9 All these forces at the same time that DTC ads
10 have come to force since about the mid 1990s, and
11 particularly after the 1997 clarification -- all these
12 forces overlap, and that makes it, has made it quite
13 difficult to tease out the independent effect of DTC
14 ads.

15 In particular, in the last few years, we think
16 there's a strong synergy between DTC ads and a rising
17 volume of free samples the doctors gave patients.
18 Literally some people see an ad, ask for the drug from
19 their doctor, and the doctor says or can say right
20 there, here's a sample, try it for a few weeks. That's
21 a powerful synergy, and as most of you probably know,
22 the increase of DTC ads is matched by the increase in
23 the volume of samples that are going to the doctor's
24 offices.

25 Point 2, because of this confluence of forces,

1 the magnitude of DTC's effects has not yet been accurately
2 quantified. That includes effects on such things as the
3 demand for drugs, prescribing trends, consumers'
4 perception of drug safety, which I think is an important
5 issue, the public's health and of course costs.

6 There is suggestive evidence both ways, that DTC
7 ads have a significant effect and that they have
8 a relatively minor effect so far, and in fact some of
9 the same evidence has been spun both ways, and Jack
10 referred to some of the evidence, and Rebecca as well to
11 the various surveys.

12 For example, I'm citing a survey that Rebecca
13 also mentioned, some observers cite survey data to
14 emphasize that only about 3 to 6 percent of people in
15 the U.S. have gotten a drug because of an ad. Sounds
16 small, but in fact that represents 8.5 to 12 million
17 adults, American adults in 2001 who received a drug as a
18 direct result of an act. Rebecca presented that data.
19 But wait, it sounds like a lot of people, but that's out
20 of 850 million physician visits in 2001 and 3.2 billion
21 prescriptions.

22 So it depends a lot when you look at this data
23 on how you want to spin it, and you really can interpret
24 it both ways, and it has been interpreted both ways.

25 Third, data linking drug advertising to higher

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1 improved access to prescription drugs through managed
2 care and particularly through PBMs. They've made it much
3 easier for us all to take our card and get a drug.

4 As that was happening, we have seen more and
5 more drugs ads, and of course some drugs have become
6 household names, so it's a real interaction. It's worth
7 noting here, though, that the pharmaceutical industry is
8 well aware that DTC ads also promote the purchase of
9 prescription drugs outside an insurance system.

10 Witness Viagra. Many men pay for Viagra out of
11 pocket, some with a prescription and some apparently
12 without. Viagra is also widely available on the
13 Internet.

14 Point 5, with respect to the FTC's question on
15 which drugs are being advertised and why, I would like
16 to stress one point which harkens back to the first
17 panel today. It's brand name drugs, not generics.
18 Question, will this change? I think it's possible we'll
19 see some generics being advertised to consumers in the
20 next few years as more blockbuster brands go off patent,
21 but it's highly unlikely that generics will ever be
22 promoted to consumers to the degree brand drugs are, and
23 I think that's unfortunate.

24 One other point here, DTC ads foster the
25 blockbuster system of drug discovery in marketing, and

1 that's not entirely bad, as Jack alluded to, but it's
2 not entirely good either. Many analysts, including us,
3 think companies have poured too much lately into
4 preserving and marketing their blockbusters.

5 Sixth point, and this is the critical question:
6 Are DTC ads harmful or beneficial on balance? The fact
7 is we just don't know. We don't know what the balance
8 is. Putting costs aside, the ads obviously have
9 positive effects, and Jack referred to some of those,
10 helping to educate consumers about diseases and alert
11 them to new drugs. That's obviously going on.

12 Just as obviously, some people are getting
13 prescriptions for drugs they don't need because of a DTC

1 more resources into monitoring the content of DTC ads.
2 I think the FDA would agree with that, and there's
3 universal consensus that they're just not spending
4 enough.

5 Recommendation 3, the FTC and FDA should more
6 formally combine forces to more carefully measure and
7 track consumer response to DTC ad including assessment
8 of problems understanding the risk information that
9 Rebecca referred to. Again the FTC and FDA should more
10 formally and more carefully measure and track consumer

1 Still though to sit around and hear conversation
2 that seems to work from the assumption that what is
3 truly motivating the pharmaceutical industry to DTC ads
4 is the desire to educate people. I don't think really
5 anybody believes that. We can talk that way. There may
6 be some incidental benefits. There may be some people
7 who learn some fragments of information.

8 But the fact that some people learn something is
9 not necessarily evidence of benefit. The question is
10 what do they learn, how selective is what they learn, do
11 they learn one thing instead of something else.

12 Dr. Inglefinger who was the editor for the New
13 England Journal of Medicine for a number of years said
14 plainly, advertisement should be overtly recognized for
15 what they are, an unabashed attempt to get someone to
16 buy something, although some useful information may be
17 provided in the process.

18 It's really hard to hear people sympathetic to
19 the pharmaceutical industry talk about their desire to
20 get information to patients when for years we've been
21 monitoring drugs in which the industry has consistently
22 tried to prevent the most dangerous of adverse drug
23 reactions from coming to public attention.

24 It's hard to sit there especially when the
25 industry objected to the patient package insert program

1 back in 1991, which would have been not the only way but
2 a very important way to get information about drugs to
3 patients.

4 We have to ask ourselves if the purpose of all
5 of this truly was education, why wouldn't you work on
6 the drugs of greater public health benefit? Why
7 wouldn't you work on the places where you really could
8 make a difference in people's lives?

9 But instead we don't see that. We see what's
10 completely predictable. We see an emphasis on the
11 conditions that are incurable, an emphasis on conditions
12 that are chronic, an emphasis usually on a crowd of
13 therapeutic classes, although sometimes an exception is
14 there for the cosmetic or lifestyle drugs, which simply
15 aren't the world's greatest public health priority.

16 We see an emphasis on the new over the old. As
17 Steve said clearly we see a complete emphasis on the
18 brand name over the generic. We see an emphasis on
19 efficacy over safety. One of the earlier tricks in the
20 DTC campaign was to put the side effects of the adverse
21 effects of a particular drug in white against a white
22 background. That's a good way of not letting everybody
23 quite see what's going on from a safety point of view.

24 Efficacy stuff of course is bright and center.
25 We've also seen a linguistic twist on this where an ad

1 for Rezulin had the benefits in English. Sorry, this
2 was in a Spanish language magazine called El Tempo, and
3 the benefits were in Spanish since it was a Spanish
4 magazine, but the brief summary appeared in English.

5 All of this suggests that the best way to
6 understand what this is all about is not about education
7 at all but really about profit, and I think unless we
8 can talk honestly about it, I don't think we can really
9 have a fair conversation about DTC advertising at all.

10 What are consumers perceptions of DTC ads? We've
11 heard something about this already. Kaiser Family
12 Foundation found that 70 percent of the TV viewers that
13 they surveyed learned little or nothing about the
14 disease, and 59 percent learned little or nothing about
15 the drug.

16 Similarly, a study in the Journal of Family
17 Practice in 2000 showed that of the possible 11 point
18 educational score, the average educational score for 320
19 DTC ads that they looked at was 3.2, and often missing,
20 not surprisingly, were information about duration of
21 use, alternatives, especially behavior alternatives to
22 drug therapy.

23 In a number of cases of course, either the
24 efficacy data was presented in a misleading fashion, so
25 the old trick of using the relative benefit of the drug
26 over the absolutely benefit of the drugs is an old trick

1 in pharmaceutical and other advertising. That's a
2 frequently recurrent thing.

3 Of course the consumers themselves are confused,
4 as was alluded to earlier. The 1999 survey showed that
5 43 percent of consumers believed that only, quote,
6 completely safe drugs could be advertised through DTC
7 and that 29 percent believed that drugs had to be,
8 quote, extremely effective in order to appear in a DTC
9 ad.

10 50 percent even believed that they had to be pre
11 approved by the government, and we've heard quite
12 clearly that that is not the case.

13 The cost element of this is also important. The
14 amount of expenditure on DTC ads is well known to people
15 in this room, some of who are spending this money, sky
16 rocketed to 791 million dollars in 1996 to 2.5 billion
17 in 2000 and now 2.7 billion.

18 The consumer pays at both ends. First we have
19 to pay for the advertising, and secondly because, as I
20 outlined at the beginning of this there's a shift for
21 newer and more expensive drugs, pharmaceutical companies
22 really don't make money on the others to the same extent,
23 we pay again because of the shift in expenditures as well.

24 I count the cost element of this is actually one

1 of the dimensions in which the evidence is most clearly
2 in.

3 I did give a bit of thought to the regulatory
4 scheme under which FTC and FDA are operating here
5 because in a way that does seem to be the theme of this
6 panel. I'm a physician, not a lawyer, so perhaps not
7 the best person to be talking about this, but my
8 understanding of the regulatory scheme is we should
9 remember that DTC ads, although we talk about them as
10 prescription ads, they're not necessarily prescription
11 ads.

12 They're over the counter that are in principle
13 DTC ads that go directly to consumer. Same thing is
14 true for dietary supplement ads. The agreement between
15 FDA and FTC says that prescription drug regulation
16 belongs with FDA, and supplements in over the counter
17 direct consumer ads, again not as important, have fallen
18 to FTC, and so my recommendation with respect to the FTC
19 would be to at least put their effort where they can
20 which would be with over the counter drugs and with
21 supplements, and there's no shortage of misleading
22 information that goes out in the dietary supplement
23 area, that's for sure.

24 Where the real power enforcement-wise is, is
25 really with FDA. As has been pointed out before,

1 despite at least 15 years of people defining such, we
2 still have no regulations for DTC ads, and we're still
3 relying on guidelines and the like that were written
4 back as a result of the 1962 efficacy amendments. These
5 are way out of date.

6 The second problem is that there are no civil
7 monetary penalties so all we get is this notice of
8 violation letters, warning letters, et cetera. Of
9 course the companies are fully aware by the time the
10 letter gets issued that already a few million people
11 will have seen the ad if it was on T.V. It's well
12 worthwhile to take the chance. The worst you get is
13 notice of violation or warning letter, which really
14 doesn't really have any strong teeth at all.

15 Indeed even when there are repeated violations
16 resulting in repeated warning letters, there still is no
17 opting for the final option which the FDA has which is
18 criminal prosecution. At least eight DTC violations for
19 Claritin, at least eight Flonase and Flo-vent, and
20 still all they get is yet another notice of violation or
21 a warning letter, still no criminal prosecution despite
22 a demonstrated pattern of conduct.

23 What really worries me about that is that there's
24 a decline in enforcement at FDA. For all of our hope of
25 what FDA might do, the fact is under the current

1 counsel's office, there is hostility I believe toward
2 really clamping down on improper advertising, and that
3 is becoming now clear in the enforcement records at the
4 FDA.

5 Notice of violation warning letters were 158 for
6 advertising, not only direct to consumer, this is for
7 everything, in 1998. But by 2001 they were down to 73,
8 and I checked the FDA's web site this morning. They
9 have data through August or so, and I extrapolated to
10 the end of the year. It will be down to 23, 23 in 2002
11 compared to 158 in 1998.

12 This is a matter of discretion. In fact there
13 was even a point at which the number of employees at

1 America and the former and founding CEO of the National
2 Osteoporosis Foundation, and I'm here today to represent
3 perhaps those conditions and diseases that have not been
4 heard on the subject of direct to consumer advertising
5 and promotion.

6 As documented in the AARP survey, there exists a
7 health information gap, which includes a medication
8 information gap, and of course as we've all said today
9 DTC advertising is really only one of many efforts to
10 address this problem.

11 I want to give you a little bit of background
12 and talk a little bit about diseases because that's what
13 DTC advertising is really addressing. First I want to
14 describe briefly a disease that is poorly understood by
15 the general public and by physicians alike, lupus.

16 Lupus is a complex autoimmune disease in which
17 the immune system goes into overdrive and begins to
18 attack normal healthy cells and tissues. It's the body
19 attacking itself. The results can be devastating
20 because no organ system is safe from this attack, the
21 joints, the heart, the brain, the lungs, the kidneys,
22 the skin, to name a few organ systems that may be
23 affected by the disease. The effects of lupus can range

1 suffer from this disease that affects both genders,
2 although 90 percent of those affected are women,
3 especially women of color. Lupus also strikes
4 children.

5 The bone thinning disease, osteoporosis,
6 accounts for more than 1.5 million fractures each year,
7 including fractures of the hips, spine, wrists and other
8 bones. This disease exacts pain and disability and
9 disfigurement and death. There are more than 50,000
10 deaths each year due to bone fractures, especially the
11 hip fracture.

12 These deaths are primarily due to infection or
13 pneumonia or blood clots that occur as a result of the
14 fracture or as a result of the surgery to fix the
15 fracture.

16 I cannot begin to tell you how challenging it
17 once was to alert consumers about osteoporosis or how
18 challenging it is today to gain public and professional
19 understanding about lupus.

20 In osteoporosis, direct to consumer advertising
21 made a major contribution to educating patients and
22 health professionals about the risks, about the
23 diagnosis and about the treatment of osteoporosis. My
24 remarks today are going to relate to two questions posed
25 by the FTC, namely the role of physicians and

1 pharmacists in advertising of prescription drugs and
2 evidence that DTC advertising is harmful or beneficial
3 to consumers.

4 Many of us can remember when physicians used to
5 be the key resource in communicating information about
6 medications to their patients, but in today's health
7 care environment, physicians have too little time to
8 spend with their patients. We've all said that today,
9 and we all know the prescription is written at the very
10 end of the visit, many times as the doctor hurries out
11 the door to see the next patient.

12 Here is where DTC advertising I think has been
13 most effective. It has helped to inform the patient
14 about major conditions and treatments and encourages
them to schedule a physician's hurriti TD7redilsto nt

1 if you live in Washington to think DuPont Circle CVS, as
2 I speak about the role of education with respect to
3 medications and pharmacists. I don't know what your
4 experience has been, but I think mine is pretty
5 typical. You take your prescription to the pharmacist,
6 and if you want, you can wait 30 to 45 minutes or you
7 can wait an hour for it to be filled or you can come
8 back.

9 In both cases it's very unlikely that the
10 pharmacist will have any time at all to speak to you.
11 If your decision was to come back for the medication,
12 you'll stand in line and just be happy that the
13 prescription is filled when you get to the counter.

14 If you had questions about your medication at
15 that point, these are replaced by other questions such
16 as: Did my prescription drug program cover the
17 medication; and by the way, what is that copay? So I do
18 think that there are issues around the time that
19 physicians have and the lack of time the pharmacist has
20 have to speak to us about our medications.

21 Unfortunately, the AARP underlines this
22 conclusion because the study points out that almost half
23 of all patients have little or no communication about
24 their medications with either of these two health care
25 professionals. Certainly policies and programs that

1 require physicians and pharmacists to discuss
2 medications with their patients are needed.

3 There is no question but that DTC advertising
4 messages could be even more educational. In many cases,
5 the ads do not describe the symptoms of the condition
6 the drug is designed to treat. The FDA regulations
7 mandate that information on adverse effects and risks be
8 presented as part of the ad, and in my view, inclusion
9 of some of this information is necessary.

10 However, I think in many cases, too much
11 information is presented, and the ad's educational value
12 and impact is diminished. DTC ads should tell the
13 balanced story, and physicians and pharmacists should
14 have the primary responsibility for discussing risks and
15 advertise effects with their parents.

16 After all, it's the physician who knows the
17 patient's medical history and can put this information
18 into context for that individual patient. Asking
19 consumers to figure out whether risks and adverse
20 effects are relevant to them I think is asking too
21 much.

22 Now, is there evidence that DTC advertising is

1 campaigns to reach the millions of people who are at
2 risk for the disease. When funds became available and
3 the organizations did produce those ads, they were aired
4 at the time the country slept. It was primetime DTC ads
5 that educated the American consumers about the existence
6 of bone density tests and treatments that made the
7 difference.

8 With respect to this disease and others, I would
9 respectfully suggest that if DTC ads were ever to be
10 eliminated there would have to be a corresponding
11 redefinition of the public service mandate of network
12 television to allow nonprofit organizations to air
13 health messages in prime time. Of course, that's not
14 the role of the FTC. It might be the role of the FCC.

15 Over the past five or six years, many factors
16 converged to establish a role for DTC advertising, not
17 the least of which was the emergence of a health care
18 system that fundamentally changed the role of the
19 physician and all other health care providers.

20 When you factor in the Internet and its
21 potential to educate and the quickened pace of
22 pharmaceutical innovation that produced more life saving
23 and quality of life enhancing drug therapies than ever
24 before, it is no surprise to me that the role and
25 responsibilities of consumers have also changed. In

1 order for consumers to benefit from the new health care
2 system, they are called to play a much more proactive
3 role in their own health care.

4 Finally, I believe there is a need to balance
5 DTC ads with more educational messages and foster
6 requirements that enable physicians and pharmacists to
7 discuss medications and their risks with consumers.

8 In addition, the public and private sector must
9 initiate major health information campaigns on diseases
10 that include material on available tests and treatment.

11 Thanks.

12 (Applause.)

13 MR. PAHL: Thank you, Sandra. Last we'll hear
14 from Richard Samp who's the chief counsel of the
15 Washington Legal Foundation.

16 MR. SAMP: Thank you. The Washington Legal
17 Foundation is a group that has been actively involved
18 over the years in promoting free speech rights under the
19 First Amendment, particularly commercial speech, and
20 that is how we first really became involved in FDA
21 issues at all.

22 We have been involved over the years in
23 litigation with FDA on First Amendment issues and have
24 won a court judgment against FDA requiring FDA to relax
25 restrictions on dissemination of information about off

1 label uses of drugs, and in fact FDA has had a pretty
2 solid record of losing virtually all of its First
3 Amendment cases in recent years.

4 I think it's that record that has caused FDA to
5 recognize that it does have to rethink what it does in
6 terms of imposing regulations in this area, so unlike
7 Dr. Lurie, I'm not looking for increased enforcement in
8 the area. Rather, I would hope that -- I think the
9 increased recognition at FDA of the important of free
10 speech is something that continues.

11 Now, I was going to spend a good portion of my
12 remarks talking about the efficacy of advertising and
13 how it does really make a difference. I think everybody
14 here is pretty much in agreement on that point. Dr.
15 Findlay is maybe not 100 percent convinced, but most
16 people here seem to think it makes a real difference.

17 Rather, the disagreement perhaps that we have
18 most strongly is whether or not it's a bad thing that
19 people have to end up paying for advertising. Dr. Lurie
20 says that the consumer ends up paying, and I guess
21 that's not surprising.

22 I think we are in agreement that if you have
23 advertising, it's because you think you ultimately can
24 make it up in increased sales later on. Manufacturers
25 are not in the business of giving away free information

1 about their products. Rather they really think they
2 have something to gain.

3 And I believe what we are seeing now in terms of
4 some increased opposition to direct to consumer
5 advertising is primarily driven by this cost factor,
6 that many states, the national government, many HMOs are
7 very concerned about rising health care costs, and they
8 really don't have any concern whatsoever about the
9 fairness and balance of ads. They don't really think
10 there are consumers who are dying as a result of
11 improper misleading information that they've gotten from
12 ads.

13 Rather, their concern is that health costs are
14 being driven up, and you see, therefore, legislation in
15 Congress, for example, to try to get rid of the tax
16 deductibility of advertising expenditures, and they're
17 obviously aimed at trying to cut down on speech, and
18 frankly I haven't seen a single proposal of this type
19 that would pass a First Amendment challenge.

20 In fact at the end of this week, I think most of
21 the organizations represented here will be filing
22 comments with FDA. We will certainly be doing so, and I
23 think that you will see a good number of the comments
24 suggesting that there are serious First Amendment
25 concerns if what we think ought to be done is cut back

1 on advertising because of the fear that it leads to
2 increased costs.

3 Now, it's not inevitable that you'll have
4 overall increased costs because of advertising, and the
5 fact that you do suggests that advertising is fulfilling
6 a real need, that people are seeing ads on T.V. and are
7 realizing that there is a product out there that, for
8 example, can treat their allergies without causing them
9 to be drowsy while they're at work, and that's a
10 significant contribution.

11 You see a lot of ads for Claritin and similar
12 products, and what you don't see is the product saying,
13 We're just as good as Claritin but we cost 30 percent
14 less, and the reason you don't see it is essentially FDA
15 bans that kind of comparative advertising.

16 Unlike FTC which just simply requires that you
17 have some substantiation for what you claim in your
18 advertising, FDA requires that you have done two well
19 controlled studies, which are the sorts of studies that
20 are required to get your product approved in the first
21 place.

22 So to make a comparative claim, to say that your
23 product is better than the other person's product or to
24 say that your product is just as good but you're
25 charging less, so therefore people should buy your

1 product requires the kind of studies that simply aren't
2 going to get done.

3 So we don't have comparative advertising, and so
4 to the extent that advertising doesn't lead to
5 competition in decreased costs, in part that is a
6 problem caused by the kinds of FDA restrictions you have
7 now on comparative claims.

8 Now, a concern that is raised from time to time
9 is that ads are not properly balanced, and pretty much

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1 generic equivalents.

2 The fact is that the price of the pioneer drugs
3 will drop precipitously and the share of the market
4 drops precipitously despite the lack of advertising for
5 any generic drugs.

6 Finally, I just want to say that people want the
7 drugs that are out there because they work, because
8 there are conditions being served by the drugs that are
9 available, and Dr. Calfee is 100 percent right. Every
10 survey shows that direct to consumer advertising is
11 increasing public awareness of the availability of
12 drugs, and we ought to be very thankful that that direct
13 to consumer advertising has now gone up to 2.7 billion
14 dollars a year, and hopefully we'll have more of it in
15 the future. Thank you.

16 (Applause.)

17 MR. PAHL: We have a few moments, ten minutes or
18 so, before the end of our time, and I guess what I would
19 like to do at this time is pose a question or two to the
20 panel, and I'll probably pose it to a particular panel
2s what member, but after that person has responded, the other

1 didn't do what the manufacturers had hoped, and as I
2 recall the latest data show that the spending in 2001
3 was not a whole lot more than it was in 2000.

4 I don't know what it is so far this year, but
5 the last I heard it was definitely not sky rocketing. I
6 don't know what the numbers are for 2002. So I think
7 that the implication of your question is right.

8 It is still a fairly small factor in this
9 market. Whether it will become a large factor I think
10 really remains to be seen.

11 MR. FINDLAY: I substantially agree with that,
12 although I use an example to show how DTC advertising
13 can really drive some markets in some therapeutic
14 categories, and it's already been referenced Claritin,
15 Allegra and Zyrtec, the three oral antihistamine drugs,
16 they comprise over 90 percent of that market. It's a
17 huge market. Those are widely, widely available drugs.

18 Millions of people suffer from allergies, and
19 DTC advertising I think with those three drugs has had a
20 profound impact on the market, driven sales and use up
21 significantly. I think just everyone agrees with that.

22 Now to your question of competition, the three
23 of them are advertising quite widely, although it's been
24 sort of up and down since '98. Some of them one year
25 spent 150 million and down to 70 million the next year,

1 et cetera.

2 I think there is competition between those three
3 and DTC.

4 MR. CALFEE: It's going to be over the counter
5 advertising for Claritin.

6 MR. FINDLAY: That's right, will become over in
7 December. I think that's an example of how DTC
8 advertising can enhance competition. Those three were
9 really neck and neck with each other, although Claritin
10 had the bulk of the market.

11 MR. LURIE: Well, that's certainly true. These
12 are drugs of no great repute really. They're not any
13 great innovation in medical care in this country, either
14 first because the disease is not life threatening at
15 all. Secondly, because there are lots of quite
16 effective drugs that are being generic for many years
17 that could have been used.

18 I think the other area of course is in non
19 steroid anti-inflammatory drugs where there's been
20 enormous promotion of Cox two inhibitors, explicit or
21 implicit claims of superiority over the Cox one
22 inhibitors, and a drive to the use of Cox two inhibitors
23 where it really simply isn't justified, and that has
24 clearly driven the market and the price of health care
25 up.

1 MR. PAHL: This question I also would like to
2 pose to Dr. Findlay to start, and it relates to one of
3 the ideas you had for something the FTC should study,
4 and that's: Do manufacturers of branded prescription
5 drugs which are about to go off patent and face
6 competition from generic drugs -- do they use DTC
7 advertising to try to maintain their market position,
8 and if they do, is that advertising characterized by
9 false or misleading claims?

10 In effect is it true advertising that's intended
11 to maintain the market position, or are you seeing false
12 and deceptive advertising that's being used to try to
13 maintain market position?

14 MR. FINDLAY: What we're seeing, is it was
15 alluded to in the panel earlier today, the tactic is
16 really not to -- once your brand drug is about to go off

1 advertised drug, but Nexium will certainly be one or two
2 most advertised drug in 2002, and those are both follow
3 up drugs to ones that dropped off patent or about to
4 drop off patent.

5 So that's the strategy of the pharmaceutical
6 industry.

7 MR. PAHL: Have you seen anything in the ads
8 that looks like they're false or misleading or do the
9 claims appear to be true and substantiated?

10 MR. FINDLAY: I'm not an expert on the content
11 of these ads. I sort of have a personal view on that
12 like we all do. I find the ads to be quite good, and I
13 find them to be relatively fair and balanced, not enough
14 side effect information for me in some of them, but I'm
15 not an expert on the content.

16 I don't think that they're -- I would say
17 they're not terribly misleading, either of those.

18 MR. CALFEE: Tom, could I add something.

19 MR. PAHL: Sure, definitely.

20 MR. CALFEE: A couple of things. One these
21 follow on drugs typically have a broader indication than
22 the ones they're replacing because they've done research
23 to get more on the label so the advertising tends to
24 emphasize that.

25 The other thing is that it remains to be seen

1 whether this strategy is going to work. I mean, right
2 now Nexium and Clarinex and so on, they're not facing
3 generic yet. They're not facing over the counter
4 versions yet.

5 The only recent case I'm familiar with where a
6 little bit of this has happened is with a development by
7 Eli Lilly of once a week Prozac, but Prozac has gone
8 generic. The managed care firms converted physicians to
9 generic Prozac very, very quickly as we saw in the last
10 session, and once a week Prozac, which is actually a
11 fairly significant innovation, that's a valuable drug
12 for a lot of people and it has done terrible in the
13 marketplace.

14 Lilly is hardly selling anyone on once a week
15 Prozac. It remains to be seen whether in Clarinex, et
16 al., will do well when they have their real battle which
17 is the battle against the PBMs that are converting
18 people to generics.

19 MR. LURIE: I would dare say you're somewhat a
20 victim of the direct to consumer advertising because
21 Prozac isn't that great a drug. The data don't
22 substantiate that.

23 MR. CALFEE: No, I'm comparing it to the older
24 Prozac.

25 MR. LURIE: I see. It's the new one that's

1 opportunity for the last word, if they would like one.

2 MR. FINDLAY: I'll respond to Peter making a
3 point, that I agree that the basic phenomena here is
4 some of the drugs that are going to -- only about a
5 hundred drugs that are advertised to consumers, a
6 hundred per year, not the same hundred.

7 It was 92 in '98, '99. It went up to 105. It's
8 about 103 now, so it's a relatively small number of
9 drugs. Are all of those drugs going to be great
10 clinical breakthroughs and represent real effectiveness
11 for patients over previous drugs or other drugs that are
12 not being advertised? No.

13 Are some of them going to be, in fact, better
14 drugs from which the public can benefit from knowing
15 about them? Yes. So I think it's a mixed bag.

16 MR. PAHL: Okay. Thank you very much for your
17 helpful comments.

18 MR. HYMAN: All right. A couple of
19 announcements. First as people are leaving, if they
20 brought stuff in with them, if they can just sort of
21 insure that there's no net gain of stuff in the room, I
22 would appreciate it because we end up cleaning it up
23 after you all leave.

24 Second, let me remind people that the deadline
25 for comment and response to the Federal Register notice

1 is September the 30th, so if you have the desire to
2 submit written comments for the record, by all means
3 feel free.

4 Let me introduce our last speaker at the end of
5 what has been an interesting and provocative two day
6 workshop. I also want to thank everyone for coming, and
7 thank all of the people on the Commission who helped to
8 make this workshop possible, and the people that aren't
9 on the Commission including speakers and panelists and
10 moderators and our partners in the various enforcement
11 agencies.

12 Now it's time to introduce our last speaker for
13 this two day workshop, Tim Greaney, professor of law
14 and co-director of the Center of Health Law Studies at
15 St. Louis University.

16 One of the things you see prevailing in
17 employment markets is that compensation is back loaded
18 for all sorts of good incentive reasons, to encourage
19 people to stay around and motivate optimal performance.
20 The family version of that is spinach first, dessert
21 later. With this in mind, I picked Tim Greaney to
22 give our closing remarks.

23 Tim has written a number of insightful and
24 provocative papers on antitrust, one several years
25 ago on hospital mergers which appeared in the American

1 Journal of Law and Medicines called Night Landings on an
2 Aircraft Carrier, and the paper, Whither Antitrust, that
3 will form the foundation for his remarks today, which
4 appeared in Health Affairs several months ago. He'll take
5 it from here.

6 MR. GREANEY: Well, thanks to David and to the
7 FTC for really stimulating a couple of days. It's been
8 a great program. I think this is what the FTC is
9 all about is bringing together people and developing
10 a base to operate from, and it's really a credit to
11 David and the staff who have done all this, and to
12 this brave stenographer who's handled two days worth,
13 thank you very much.

14 Let me make a couple remarks. First of all, I
15 give you a personal disclosure about my personal health
16 history. I have a genetic defect. I'm a life long Red
17 Sox fan, and that makes me constitutionally incapable
18 for me to see the glass as half full, and I'm afraid
19 I'll have some gloomy assessments about antitrust
20 enforcement, and I offer that by way of excuse.

21 My normative perspective though is, I won't
22 repeat it, I'll just incorporate by reference what Bill
23 Kovacic said earlier, one of our really outstanding law
24 professors in the area and someone who knows what he's
19

1 enforcement has been the FTC's crowning achievement, I
2 agree with that completely. I think it's a feather in
3 the cap of what the FTC has done.

4 There are countless economic studies I think

1 what antitrust can do about it.

2 Let me first deal with probable claims for
3 antitrust relief, relief from antitrust law. It's
4 something that is not new. I think it's something that
5 has occurred in every era of antitrust. In the late 70s
6 and early 80s when antitrust in health care was just
7 beginning, we heard claims that it was needed. You
8 needed special exemptions, et cetera, to preserve
9 professional sovereignty, to preserve the supremacy of
10 state and federal regulation.

11 In the 1980s the ground shifted a little and we
12 heard that there was legislation regulation needed so
13 PPOs could form. Maricopa was said to be blocking PPOs.

1 They produced the FTC/DOJ policy statements. They also
2 helped contribute to state hospital cooperation laws,
3 state laws regulating managed care, physician collective
4 bargaining laws more recently.

5 How do we appraise those results? Well, I've
6 given them grades. I give the Health Care Quality
7 Improvement Act a B, policy statements A minus,
8 cooperation laws C minus, managed care laws C plus, and
9 the collective bargaining laws an F.

10 I'm a pretty easier grader as it turns out. I'm
11 going to do what law professors don't do which is tell
12 you why they give the grades. We're sort of a black
13 box. We don't have to disclose what we're grading on,
14 and here's my grading key, and really it's one of the
15 best articles I can commend to you. It's actually a
16 chapter in a book soon to be published by Peter Hammer
17 called Medical Antitrust Reform, Arrow, Coase, and the
18 changing structure of the firm.

19 He says we have to change the competitive norm
20 against whether it is doing something that promotes
21 consumer benefit, promotes consumer welfare, by
22 ameliorating some kind of market failure, and is it well
23 designed to advance social welfare.

24 I'm not going to have to go into why I think one
25 does and one doesn't, but I think you can see there's

1 really questions about whether some of these state laws
2 are really addressing a real problem, what the market
3 failure, their design it at best ambiguous, and the
4 remedy is certainly not designed to correct a market
5 response.

6 Anyway, that's my norm. Those are my grades and
7 I'm sticking with them, but I'll talk more about the
8 policy statements because I think they are a major
9 development and something that needs to be talked about.

10 Let's start with some success stories about
11 antitrust. I have a picture here of someone -- I didn't
12 bring my seating chart. I should call on someone.
13 Anybody who knows who that is? It's not the poster guy
14 for diet in a bottle. You might have thought that.

15 That's former Judge Taft who wrote Addyston Pipe,
16 one of the great decisions in antitrust history, and I
17 thought that would be a good frame for our success
18 stories.

19 The success stories I think, and I'm going to go
20 very quickly through them because I want to dwell on the
21 negative, the policy statements really have contributed
22 to understanding advanced knowledge, spread the word
23 outside of the Beltway and I think improved the
24 functioning of the legal advising system which is really
25 what we're about here. We're about improving lawyers'

1 ability to advise clients.

2 Antitrust has done a great job in weeding out
3 the chaff. Don't forget it has dealt with those
4 hundreds and hundreds of staff privileges cases, which I
5 share with Peter, probably the only one in the room
6 that's read all of them. I read them for writing my
7 treatise. They're spurious, and antitrust, there's been
8 four successful cases in those hundreds of cases,
9 encouraging integration, promoting means by which firms
10 can integrate, a need to do it, curbing cartel
11 activity. I think the FTC in particular, its activities
12 its repeated cases in this area really are an important
13 contribution.

14 I think the pharmaceutical industry, things
15 we've been talking about, are exactly what this agency
16 is supposed to be doing. If we want to apply the merger
17 guidelines phrase, timely, likely and sufficient, that's
18 the kind of enforcement I think you want. It was
19 timely. It was likely to improve competition, and it
20 was an important step forward.

21 Finally I'll just say the staff here is really
22 something to be proud of and something that has really
23 improved the way things work.

24 Well, what have we heard the last couple days?
25 I think we've heard a little bit of the murder on the

1 Orient Express here. We've heard the blame being pushed
2 around as to who's responsible for competition's failure
3 to curb costs in health care, and we've had sort of the
4 physicians, the hospitals and managed care pointing to
5 each other, Don't sue me, sue the guy behind the tree.

6 We've heard them talking about whose
7 concentration, whose activities have spurred the spike
8 in health care costs.

9 Let me offer some other places where we can
10 look, not that they are not to blame in some sense. I
11 mean, there is higher pricing of people who have either
12 acted through cartelizing or in response to natural
13 forces of their increased market concentration, but let
14 me mention some problems we have.

15 We have a problem with respect to the
16 concentration spike because of problems of detecting
17 mergers, joint ventures, detecting cartels. If I want
18 to leave a message today, I think the lack of litigation
19 is a big problem. It is a big problem.

20 I know lawyers are not supposed to complain
21 about the lack of litigation, but my tag line here is
22 that advice, policy statements, speeches, advisory
23 opinions, et cetera, have a diminishing shelf life if
24 it is that not backed up by litigation. I think the
25 policy statements are a great achievement, but I think
26 not backed up by litigation you can see their weakening

1 that extent, and the piece I'm working on now really
2 talks a little about or friends from Cook County,
3 Illinois, the Chicago school, and what they're teaching
4 has done to infiltrate thinking, and I'm afraid in the
5 health care area, adhering slavishly to the Chicago
6 template is a mistake that the courts are making, and I
7 think given market failures and other things, we have
8 those problems.

9 In any event, the other bad news is antitrust
10 has very little to say about some of the key areas that
11 are affected now. Oligopoly for one, antitrust has
12 almost nothing anything to do with oligopoly and
13 monopsony has its own problems.

1 journal, St. Louis Law Journal, but it's a piece he
2 wrote on the MedSouth decision, the MedSouth advisory.

3 He really does talk, I think, in very good terms
4 about the problems we have with the Rule of Reason and
5 the problems of what he calls an on off switch. It's
6 either Per Se Rule and illegal or Rule of Reason and
7 legal, the old defendant's paradise argument, and I
8 guess this blurring of the standard is the problem we
9 have, that Judge Easterbrook captured it well when he
10 said, "When everything is relevant nothing is
11 dispositive."

12 Okay. Well I don't want to leave out the
13 private bar, and this brings me back to my message, How
14 effectively are policy statements conveying what the
15 boundaries of the law are? Is there a mentality out
16 there that any merger is worth trying? We have almost
17 negotiated rulemaking now. That turns into negotiated
18 conduct. I'm all for advisory opinions and policy
19 statements, but I think we need to go further.

20 You can look at this. I was asked to predict
21 the future, and I've tried to list some of the areas
22 where we see cases developing now. I'm working on a new
23 edition of my case book, so I have to collect as many
24 cases as I can.

25 But clearly we have provider cases, hospital

1 physician disputes. With concentrated markets we have
2 exclusive contracting problems that really do fit the
3 model of what is problematic. We have hospitals with
4 significant market power engaging in exclusive
5 contracting in areas where there is legitimate
6 foreclosure in physician markets.

7 We see that in other areas, so I won't go
8 through the litany of possible combinations there are
9 out there, except to say there are cases that at least
10 on their face really do make some economic sense, but
11 I'm not sure private parties are sufficiently incented
12 to bring them in all cases.

13 Where do we go? Can I cut the Gordian knot?
14 Well, no, as I used to say when I worked for the
15 Antitrust Division, that's beyond my pay grade, but I'll
16 throw out a few ideas, a few thoughts here.

17 My bottom line which I signaled earlier was that
18 policy statements, et cetera, are good but if they
19 become advisories, if they become -- if everything is
20 negotiable, I'm not sure that a message is sent that
21 will really revitalize antitrust.

22 So I think the FTC has got to get involved as it
23 has in the past in Amicus filing in trying to get the
24 private cases that are meritorious, more successful.
25 Again I'm an alumnus of the Antitrust Division, but I do

1 believe there is a law enforcement role to be played.

2 I have to say I've been hearing about criminal
3 enforcement for many years since I left the division,
4 and I'm still waiting to see it. I look at some of
5 these physician cartels at least as described in some of
6 the releases, and I'm wondering: "Where are the criminal
7 referrals, where are the referrals to Justice for
8 criminal prosecution?"

9 Some of these cartel activities are not all
10 together different than some of the international
11 cartels that the division prosecutes, and in some cases
12 it certainly is appropriate to send a message, and if
13 you want to change the nature of advising between lawyer
14 and client, I think that is a way to do it.

15 In today's environment where we hear that the
16 people at WorldCom and elsewhere are to be prosecuted
17 to the fullest, I think people who knowingly and
18 intentionally violate the law at significant costs to
19 consumers should be prosecuted criminally.

20 Are there other avenues? I think the states
21 have a role to play. I think the states really have
22 their hand on the pulse of their local markets. They're
23 perfectly situated to do it. A lot of states are
24 increasing their staffs, but I think they need some help
25 from somebody, and I know there have been cooperative

1 cases filed.

2 In the Whither antitrust piece in Health
3 Affairs, I suggest the outrageous, that maybe even
4 regulatory reviews by state agencies, maybe a second
5 best alternative to litigation, since litigation is
6 expensive and hard to come by. Maybe regulatory
7 mechanisms like the State of California has for its non
8 profit mergers is appropriate, returning to my theme
9 that policy statements have some advantage, but
10 guidelines I think are -- we may have reached the point
11 where they are necessary.

12 There is a vast and increasing economic
13 literature that's growing out there that might help
14 inform thinking in these areas. There's a lot being
15 written on market definition and integration that might
16 be of help and also moving towards more targeted
17 research. Final point -- supporting targeted research
18 here that will help inform both courts and legislatures.

19 We have a problem of lag. Something gets
20 written, but it takes years to turn into decisions in
21 the Federal Courts.

22 Finally I have a note that there is a -- I think
23 the rationalization of industries makes very good sense,
24 and the FTC taking the lead in health care is a very,
25 very good idea, but there is a concern with

1 jurisdiction.

2 70 percent of the hospitals are not for profit.
3 Much of what they do will be out of FTC's jurisdiction,
4 and somebody's got to watch that. Criminal enforcement
5 is the Justice Department's responsibility. I hope
6 those holes will be well plugged. I have a concern
7 given frankly the Antitrust Division's history.

8 Well, at the end, I give you some reading to do,
9 part shamelessly advertising my own reading, and Peter
10 Hammer's article I mentioned is an outstanding piece,
11 and once again Commissioner Leary has really put
12 together one of the most thoughtful pieces I've read.
13 I'm sure he would be willing to share it with you, even
14 though we haven't published it. Yet we don't make any
15 money on our law journal, so I'm happy for you to get it
16 directly from him.

17 It really does deal with some of the key
18 problems of assessing conduct in the health care
19 industry, trying to appraise the influence of quality
20 when you make the assessment of net competitive effects,
21 and it really is an excellent, excellent article.

22 Thank you for your attention, and, David, thank
23 you for a wonderful conference. It was a well
24 conceived, well executed conference.

25 (Time noted: 5:23.)

