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1 NEW JERSEY ATTORNEY GENERAL'S ADVISORY COMMITTEE
ON PHYSICIAN COMPENSATION ARRANGEMENTS

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4 IN RE: :
Public Hearing. : TRANSCRIPT OF
PROCEEDINGS

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P R E S E N T:

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1 P R E S E N T: (Continued)
2 MAHMOOD H. CHEEMA, M.D., Board Member
Livingston Orthopedic Group

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1 DR. BLANKS: Good morning, everyone.
2 Thank you for coming this morning. We're here to
3 receive public comment. I just wanted to give you
4 to start with a little background about the Advisory
5 Committee.

6 For a number of years now,
7 information's come to the attention of the public
8 and the Attorney General, Board of Medical
9 Examiners, from the courts, the media and the
10 professional literature that describe a variety of
11 relationships between the physician community, the
12 medical community, and the pharmaceutical and
13 medical device industry. These relationships
14 involve compensation arrangements which can be
15 perceived to cause or actually in some cases cause
16 competing interests which can result in unduly
17 influencing medical care or medical practice.

18 The Attorney General and Board of
19 Medical Examiners convened this Advisory Committee
20 to bring together persons knowledgeable about the
21 details of these relationships who represent a wide
22 variety of perspectives on these issues. And this
23 Committee was brought together to study the
24 situation in depth to determine the extent of the
25 problem and whether or not response was required

0004
1 that would be in the public interest.

2 As part of that study, we're
3 convening this informal conference to solicit public
4 opinion about these issues. Specifically as
5 described in the notice, we're trying to elicit
6 comment about the various types of compensation,
7 services of value, which would include gifts, meals,
8 provision of sample medication, sponsorship of
9 educational conferences and training, support of
10 clinical research, consultantcies, and charitable
11 foundations. We are also seeking from the public
12 suggestions for ways to deal with the issues that
13 are raised and any analysis or ramifications that
14 might result from suggested solutions.

15 I'd like to thank everybody again for
16 coming, especially the members of the Committee who

17 were able to take off again today from their regular
18 work to come and hear this testimony. And I'd like
19 to proceed at this time by having the Committee
20 members who are present introduce themselves.

21 MR. DE MARZO: My name is Larry
22 DeMarzo. I'm the Acting Director of the Division of
23 Consumer Affairs. And just for a brief moment, I'd
24 like to just welcome you to the Division. I
25 apologize for the pole in the center of the room,

0005

1 nothing we could do about that.

2 But again, to reiterate some of what
3 Mary said, this is an issue of tremendous importance
4 to the Attorney General. I'm not exaggerating by
5 saying that. It's an issue she's really interested
6 in. This Committee has approached the topic with a
7 totally open mind. We solicited members from
8 throughout New Jersey, from the pharmaceutical
9 industry, from hospital associations, from public
10 interest groups. And today, just in keeping with
11 that theme, we are looking for comments from members
12 of the public, members of other groups, and again,
13 welcome to the Division.

14 MS. GOLDMAN: Good morning. My name
15 is Lisa Goldman. I am an industry representative on
16 the Task Force appointed by the Health Care
17 Institute of New Jersey. The Institute appreciates
18 the opportunity to participate in the Task Force on
19 behalf of all of its members who are dedicated to
20 developing innovative medicines and devices to help
21 improve life and the quality of life in New Jersey
22 and around the world.

23 MR. PARANICAS: Good morning. My
24 name is Dean Paranicas. I'm another industry
25 representative from Becton Dickinson & Company,

0006

1 B.D., a medical technology company located in
2 Franklin Lakes. And Lisa very articulately
3 expressed my sentiments as well. So we welcome
4 you. We look forward to hearing your comments.

5 DR. CHEEMA: I am Mahmood Cheema.
6 I'm an orthopedic surgeon. I'm a member of the
7 State Board of Medical Examiners. I'm in private
8 practice in Livingston associated with
9 St. Barnabas. I'm here to listen and learn.

10 MS. JOYCE: I'm Sharon Joyce. I'm an
11 Assistant Attorney General representing a number of
12 professional boards and other agencies in
13 government. I'm really not on the Task Force, but
14 I'm certainly interested in listening to what
15 everybody has to say today. Thank you.

16 MS. KEAN: Eileen Keene with the
17 Medical Society of New Jersey, I am sitting in for
18 Michael Kornett who is the CEO of the Medical
19 Society who wasn't able to attend this morning,
20 representing the physicians of New Jersey.

21 DR. BLANKS: Once again I want to

22 thank everyone for coming. We have scheduled
23 sixteen speakers. And if there's time left, we will
24 hear from unscheduled speakers. I'd like to remind
25 you at this time to contain your comments to the

0007

1 very generous ten minutes that we've planned and
2 allotted. We will have time for the Committee to
3 ask questions. So we'd like to make sure we leave
4 time for that. So we would appreciate you abiding
5 by the ten-minute limit.

6 And we can go ahead and get started
7 now. Our first speaker is Marilyn Askin, the Chief
8 Legislative Advocate for AARP New Jersey.

9 MS. ASKIN: I just want to say hello
10 to Dr. Cheema. I'm a former patient.

11 Good morning, all. My name is
12 Marilyn Askin. I'm the Chief Legislative Advocate
13 for AARP New Jersey, a nonprofit, nonpartisan
14 membership organization that helps people 50 and
15 better have independence, choice and control in ways
16 that are beneficial and affordable to them and to
17 society as a whole. We have 1.4 million members in
18 New Jersey and 39 million members nationwide.

19 The overwhelming majority of American
20 doctors have some form of relationship with
21 representatives of the pharmaceutical industry,
22 despite the potential for conflict of interest,
23 according to a study reported in the April 26, 2007,
24 issue of the New England Journal of Medicine. In
25 reality, practicing physicians act as gatekeepers

0008

1 between their patients and the pharmaceutical
2 companies aiming to hook those patients on their
3 drugs. The study reports that 94 percent of doctors
4 receive food in the workplace or prescription
5 samples, and more than one-third are reimbursed for
6 costs associated with professional meetings or
7 continuing medical education, and more than a
8 quarter receive honoraria for consulting, lecturing,
9 or enrolling patients in clinical trials. The
10 relationship apparently benefits physicians and the
11 industry, but the concern of AARP New Jersey is to
12 what extent does this relationship benefit patients
13 and affect the care they receive.

14 The industry employs an estimated
15 100,000 sales representatives called detailers who
16 visit the waiting rooms of the nation's 311,000
17 office-based physicians where more than 600,000
18 physicians practice medicine. These detailers earn
19 about 81,000 to 150,000 a year, according to the
20 Wall Street Journal, July 15th, 2005. The marketing
21 technique is used by companies to educate
22 prescribing health professionals about the benefits
23 of specific drugs. The practice is used
24 predominantly by brand name manufacturers. The
25 detailers do not actually sell drugs, they explain

0009

1 or detail their products in hopes of persuading
2 those with access to a prescription pad to prescribe
3 the drugs.

4 The process frequently begins when
5 the pharmaceutical company purchases the prescribing
6 history of individual physicians usually without the
7 consent or knowledge of the physicians. The
8 information is used by the detailers to conduct
9 targeted sales pitches to the doctors and the direct
10 mail marketing. A single detailer can generate
11 about \$1.9 million in sales, according to a report
12 by Lehman Brothers.

13 Detailers typically arrange for an
14 appointment by the prescriber in the same way a
15 patient makes an appointment to visit a doctor. The
16 detailer may pay for the doctor's time. Many
17 detailers also perform drop-in visits where they
18 walk around the office and hand out free toys, pens,
19 tissue boxes, clip boards, and food to office staff,
20 as well as doctors. Detailers also often provide
21 gifts, which include sports tickets, dinners,
22 watches, trips, and consulting fees.

23 High-prescribing doctors may be asked to make a
24 presentation in support of the use of a particular
25 drug, and the manufacturer will pay for the flight,

0010

1 lodging, food, and transportation for the entire
2 family, as well as fees for their presentations.

3 AARP is not opposed to drug industry
4 detailing, as long as there is full public
5 disclosure of detailer marketing costs.

6 (Mr. Knowlton enters the room.)

7 AARP supports manufacturers educating
8 prescribers about the benefits and risks of a
9 specific medication, but at the same time supports
10 public disclosure of any financial or other
11 incentives given to prescribers and consulting
12 relationships between the industry and the
13 prescribers for consumers and others who pay for
14 prescriptions. Full disclosure makes the
15 relationship transparent and allows them to make a
16 reasonable determination of the possible impropriety
17 of undue influence over prescribers.

18 Beginning with Vermont, a number of
19 states have enacted or are considering drug
20 marketing disclosure legislation as part of their
21 efforts to control drug costs. Drug disclosure
22 costs highlight the huge expenditures that drug
23 companies make to promote predominantly high-cost
24 brand name medications to doctors, pharmacists and
25 other providers. Once these promotional

0011

1 expenditures are made a matter of public record, the
2 case for offsetting their influence with
3 countervailing measures becomes compelling.

4 Drug companies spend so much on
5 promotion because it pays off in sales of their

6 high-cost drugs. Evidence-based research, preferred
7 drug lists, and counter detailing can ensure that
8 prescribers consider appropriate lower-cost
9 medications. Composing the gifts, payments, travel
10 and entertainment that the drug industry lavishes on
11 doctors and other providers and putting a total
12 dollar figure on them may also have a deterrent
13 effect at least with respect to some of the more
14 extravagant practices.

15 Drug marketing disclosure laws
16 represent an important element in AARP's
17 prescription drug affordability campaign. They not
18 only add a solid fact-based dimension to cost
19 containment proposals, but also strengthen the hands
20 of proponents seeking to cut drug costs. These
21 marketing disclosure laws can eliminate one of the
22 reasons why prescription drugs cost so much. The
23 disclosure laws, particularly those which track
24 payments received by individual prescribers, allow
25 state governments, policy makers, and consumers to

0012

1 gauge the direct impact of marketing on prescribing
2 patterns. They help policy makers determine the
3 need for countervailing measures, such as
4 evidence-based research, preferred drug lists, and
5 counter detailing. They can help evaluate the
6 cost-effectiveness of countervailing measures.

7 AARP strongly supports requiring the
8 State Attorney General and/or the Department of
9 Health and Senior Services to publish information
10 about the financial or consulting relationship
11 between pharmaceutical companies and prescribers.

12 Thank you for permitting us to
13 testify in behalf of our members.

14 Any questions? And hi, Dave
15 Knowlton.

16 MR. DE MARZO: I have a
17 comment/question.

18 MS. ASKIN: Sure.

19 MR. DE MARZO: For those in the
20 audience who don't know, AARP was instrumental in
21 allowing the Division of Consumer Affairs to -- in
22 having a law passed that mandated that the Division
23 of Consumer Affairs put a prescription drug price
24 registry on-line, which we did, and we launched with
25 the Governor not too long ago, and Marilyn was there

0013

1 at the launch. And we have it up and running right
2 now. And what it does is it compares -- depending
3 on where you live, you can put in the name of a
4 prescription, your zip code, and it will bring up
5 all the pharmacies in your area and how much each
6 pharmacy charges for that particular prescription.
7 And it's thanks to AARP that the legislature passed
8 that, the Governor signed it, and we were able to
9 put it on-line.

10 We've been toying with the idea of

11 perhaps making that -- well, there's some kinks
12 that have to be worked out. As we talked about
13 earlier, the site is up and running, but we've been
14 talking about the idea of perhaps making that more
15 user-friendly for physicians to compare the prices
16 that their patients will have to pay for different
17 prescriptions.

18 MS. ASKIN: Great idea.
19 Incidentally, AARP provided some political muscle,
20 but the initial research was done by David
21 Knowlton's group. They're the ones who went around
22 and determined that some pharmacies a block away
23 from each other were charging differences in \$70.00
24 a prescription. Most seniors take about four or
25 five a month. And that is substantial. So we

0014
1 worked very closely with David's group to make this
2 a reality.

3 One thing you also didn't mention,
4 that a lot of our members or many people are not
5 computer savvy, and why this website is so good and
6 so popular is that we also have an 800 number, and
7 we also have it in Spanish. So it is really the
8 best registry in the nation, and we thank the
9 Department of Consumer Affairs for working with us,
10 you know, to set it up and to save our residents a
11 lot of money.

12 Any other questions or comments?
13 DR. CHEEMA: I just want to say that
14 was an excellent presentation.

15 MS. ASKIN: Well, thank you so much
16 Dr. Cheema. And you're an excellent doctor.

17 DR. BLANKS: Okay. Next speaker.
18 Mr. Knowlton, you want to introduce
19 yourself?

20 MR. KNOWLTON: Marilyn didn't do it
21 for me?

22 DR. BLANKS: Well, who you're with.

23 MR. KNOWLTON: I'm Dave Knowlton.
24 I'm the President of New Jersey Health Care Quality
25 Institute.

0015
1 DR. BLANKS: And if anyone is
2 interested, we do have lists of the full Committee
3 membership for you.

4 MS. HAMS: Thank you very much. I
5 really appreciate being here today. I'm Marsha
6 Hams. I'm the Assistant Director of The
7 Prescription Project, which is a project funded by
8 the Pew Charitable Trust, and we're based at
9 Community Catalyst, which is a national nonprofit
10 advocacy organization. We're based in Boston, and
11 we work with consumer organizations and a broad
12 range of physicians and other people concerned about
13 the -- about health reform around the country.
14 We're also partnering with the Institute on Medicine
15 as a Profession, which is based at Columbia College

16 of Physicians and Surgeons on this project.

17 The project is really focused on this
18 whole area of the influence of the industry on
19 physicians and on medical organizations and health
20 care institutions. We're hoping to change the
21 situation by changing the ways in which the medical
22 profession deals with the pressures from industry
23 and its marketing behavior.

24 Now, the industry's interest, of
25 course, is to market its product, but the medical

0016

1 profession, individual physicians, academic medical
2 centers and public policy, public peers and private
3 peers have a decision to make about how they respond
4 to that marketing. We think this marketing has
5 a -- it's really contributed to out-of-control
6 costs throughout the system. We have a great deal
7 of influence by the industry on our public policy
8 makers, and this influences some of the responses to
9 the pressures. And we know that consumers are
10 having a very difficult time affording their
11 medications, and Medicaid departments, Medicaid D,
12 and other public payers are having difficulty paying
13 for drugs as well.

14 The representative from AARP did an
15 excellent job of describing the actual ways in which
16 the pharmaceutical detailers interact with
17 physicians. The industry spends about \$7.2 billion
18 per year marketing to physicians. They spend about
19 4.8 billion marketing to consumers on all those
20 wonderful ads we see every night on television. And
21 there are about 90,000 to 100,000 sales reps, or one
22 for every nine physicians out there in the field.
23 They're providing gifts, lunches, trips, educational
24 grants, entertainment, free samples, and a whole
25 variety of inducements in order to change the

0017

1 prescribing behavior of physicians. It's estimated
2 that about \$1 billion is spent on gifts alone at
3 this point for physicians. They're utilizing very
4 well-designed techniques to approach physicians.

5 I actually have here a Merck training
6 manual that became public due to a court case and
7 details how there are about twenty or thirty metrics
8 that the detailer gets about their physicians and
9 their Merck potential. And there's other examples
10 here of what the plan would be for a particular
11 physician.

12 For instance, with one physician,
13 they reviewed the new acute pain data for Vioxx.
14 The physician indicated she would consider speaking
15 for Merck on the benefits of Vioxx with her
16 colleagues. So there's a direct relationship
17 between what happens in the office and the way in
18 which physicians are used in the process of
19 marketing itself.

20 The focus of marketing to physicians

21 and to the public is on the newest, most expensive
22 treatments. You don't see ads for generics.
23 There's no incentive for generic companies to
24 advertise, since they are all producing the same
25 generic. And that means that about fifty of the

0018

1 most heavily marketed drugs accounted for 50 percent
2 of the increased sales in drugs.

3 There's a problem not only with
4 costs, however, but also with quality, and that's
5 come out in some of the -- I think Vioxx is
6 probably the most famous example at this point. But
7 what you have is an industry that -- whose business
8 plan has really been focused on marketing for drugs
9 that have the broadest possible universe of
10 patients, painkillers being one of them. And even
11 though there was evidence of problems with Vioxx,
12 they continued to market it. It was spending 500
13 million annually to market it, and it brought in
14 about 1.7 billion in sales when it was pulled from
15 the market, and about 55,000 deaths attributed to
16 the use of Vioxx. And Vioxx was actually even, at
17 best, only appropriate for a very narrow band of
18 patients, that's what the literature showed. And
19 the cardiac impacts had been hidden.

20 Marketing is about 30 percent of the
21 overall cost of drugs, about twice that spent on
22 R&D. So I think that it really has distorted the
23 entire way in which the industry operates.

24 There are a number of -- a whole
25 range of solutions to this problem from our point of

0019

1 view. We're working, as I said, with academic
2 medical centers, medical professional societies,
3 purchasers, physicians and policy makers to
4 implement solutions. There are now some academic
5 medical institutions that have adopted voluntary
6 standards in their institutions. These are the
7 institutions that train our physicians. And we
8 think that that's very important for them to do.

9 We are promoting specific standards
10 around gifts, meals, samples, representatives on the
11 medical school campus, continuing medical education,
12 consulting, speaking and honoraria. In the handout
13 that is in the packet, it details what the new
14 policies are at Boston Medical Center, for instance,
15 that just were put into effect about a
16 month-and-a-half ago. We've been working closely
17 with their committee to help them implement this.
18 For instance, they're not going to allow clinicians
19 to accept any gifts, no meals on campus, there's
20 discretion off campus, samples can only be
21 distributed through the pharmacy, no reps permitted
22 to interact with trainees on campus.

23 There must be fair market
24 compensation for consulting. These are the kinds of
25 things that we think can be implemented in this

0020

1 sector. The University of Pittsburgh just came out
2 with excellent guidelines this week, and we've seen
3 Yale, University of Pennsylvania, Stanford,
4 University of California, Michigan, Pittsburgh as I
5 said, UConn. We think there's -- that these
6 institutions should be moving in this direction.
7 And there should be leadership throughout the
8 medical profession in doing this. However, academic
9 medical centers only reach a certain proportion of
10 patients -- of physicians. They don't reach the
11 physician in the community that is not working at
12 the academic medical center. And so we need public
13 policy changes as well in our view.

14 And we're hearing from within these
15 institutions from people who are champions that they
16 want the outside pressure, they really want public
17 policy makers like you looking at this issue. It
18 makes their job easier when they're trying to do
19 something on a voluntary basis.

20 So we've had state legislation on
21 gift bans and disclosure, starting in Minnesota in
22 '93, and they've tightened this up in the last
23 couple of years, and they are the only state right
24 now where the industry has to disclose all of the
25 payments to physicians, including the name of the

0021

1 physician, and that is now public. And the Chair of
2 their Board of Pharmacy is Cody Wiberg, who is an
3 excellent resource if you'd like to speak to him.
4 He's been very aggressive in making these payments
5 public, making an easily accessible website now
6 which hadn't been done for many years. And now
7 they've been able to match up the money that's spent
8 on specific physicians with utilization and
9 Medicaid. So really the point of disclosure is both
10 public pressure on the physician, but to allow
11 public peers to say how is this actually affecting
12 prescribing.

13 Vermont, Maine and West Virginia also
14 passed laws.

15 There were seventeen bills introduced
16 last year. Congress is now interested in this.
17 There's a proposed Physician Payments Sunshine Act
18 that Senators Grassley and Kohl have proposed,
19 filed, and the House is interested as well. And we
20 think there may be continuing investigation and
21 action there.

22 There are a number of other areas in
23 terms of public policy that we think could be very
24 important. These would support not only improving
25 conflict of interest standards, but also finding

0022

1 ways to improve prescribing and access of physicians
2 to the right kind of information that they need for
3 prescribing and thinking in terms of what -- I'll
4 name a couple of those.

5 Academic or counter detailing are
6 organized programs to bring evidence-based, unbiased
7 information to physicians in their offices to help
8 them make better decisions. This is being piloted
9 with elder programs in Pennsylvania. They're
10 finding that it's saving money, but it's also
11 improving quality of care. This in no means -- by
12 no means do we mean that all patients, one size fits
13 all. Sometimes the term "evidence-based medicine"
14 has been distorted to somehow it's being said that
15 it means that there's -- two minutes -- that
16 there's -- that all patients should only have
17 access to certain medications. We don't think
18 that's the case at all, but that we should look at
19 the best evidence and not marketing when physicians
20 are making decisions.

21 There's statutes now passed in
22 Vermont and Maine on these academic detail programs,
23 and they're starting their planning.

24 So in terms of looking at the role of
25 Attorneys General and perhaps Boards of -- the

0023

1 Board of Medical Examiners and other Boards of
2 Medicine, it seems that these -- that gifts
3 regulation could be done through Boards of Medicine,
4 that the Medical Examiner could maintain the
5 database that, for instance, the Board of Pharmacy
6 does in Minnesota. There could be a requirement to
7 disclose the funding for continuing medical
8 education credits, which would be very appropriate,
9 since that's a role in terms of licensing. And we'd
10 like to see a requirement that at least half and
11 then perhaps more, a larger percentage of CME
12 credits be free from industry funding, perhaps
13 ramping up to 70, 80 percent being required, because
14 even in spite of regulations by ACCME, there's clear
15 evidence that industry supported CMEs.

16 In closing, providing and prescribing
17 information to physicians could be made available
18 through Boards for nonindustry-funded CME. And then
19 in a wider framework, I think there's a role for
20 looking at the conflict of interest standards in all
21 public institutions. They could align with public
22 employee conflict of interest standards.

23 Public purchasing. No one
24 responsible for any public -- any purchases of
25 prescription drugs in public institutions should

0024

1 have conflicts of interest. And more could be done
2 to investigate influence of the industry on CME.

3 And I think one other area that would
4 be fruitful is to look at the conflict of interest
5 with medical organizations that are determining
6 treatment guidelines. Many of the medical
7 professional organizations have a great deal of
8 influence on the standard of care and they do not
9 have conflict of interest standards, and this

10 affects public purchasing of cost of drugs and
11 prescribing.

12 Thank you very much.

13 DR. BLANKS: Questions?

14 MS. JOYCE: I've read some studies
15 about programs that may be introduced into the
16 educational system for doctors, either at medical
17 school or in residency training, that may cause them
18 to be more alert to influence and to be I think the
19 word they've used is inoculated, to be cognizant of
20 what it's doing. Do you have any information about
21 those kinds of curriculum changes that --

22 MS. HAMS: I think there are
23 curricula that have been designed. For instance,
24 there was a major settlement curricula on the
25 Neurontin case, and the grants from those -- the

0025

1 funds from that court case have been used to design
2 curricula like this. And I think that's an
3 excellent way to support this. You also find that
4 in some hospitals where residents are training, that
5 there's also academic detailing by the
6 pharmacies -- by the pharmacist to physicians
7 working in those institutions, and that's another
8 way to give them advice about their prescribing.

9 MS. JOYCE: Does your organization
10 have anything that they've compiled about the
11 Neurontin-funded projects that came forth?

12 MS. HAMS: We haven't put that
13 together, but we have been looking at that. Because
14 I think there are a number of programs that are very
15 important. For instance, one of the sources for
16 nonindustry-funded CME is called PharmedOut. That's
17 the name of their website. It's listed in my
18 materials. And that would be one source for
19 physicians. And it's specific clinical areas and
20 sites. One of the grants supported some of the work
21 of Dr. Jerry Avorn at Harvard who has designed a
22 program in Pennsylvania.

23 I want to share one thing with you.
24 I was just reminded on my way over here. I just was
25 walking from the train station, had talked to a

0026

1 young woman about looking for directions, told her
2 where I was going, and she said, oh, a friend of
3 hers, she's from New York, who is a physician
4 pharmacy rep just offered to pay for her wedding.
5 Now, I hadn't heard that before, so I'm very anxious
6 to look into that. So can you imagine a sponsored
7 wedding with all your physician friends, and perhaps
8 booze is in the front yard. But anyway, I hadn't
9 heard that.

10 MS. KEAN: Can I make a comment?
11 Let's be careful about how we repeat hearsay,
12 because that is hearsay. And we haven't validated
13 that. Because I just want to --

14 MS. HAMS: Absolutely.

15 MS. KEAN: I know we're going to have
16 fair and balanced testimony today, but I just want
17 to offer that comment. So let's not forget that the
18 reason why we have such high health care costs in
19 this country and in the State of New Jersey is
20 because there are great successes and people are
21 living longer and medicine is expensive and a lot of
22 these prescriptions are helping us all live a lot
23 longer. So let's not be too doom and gloom.

24 MS. HAMS: Absolutely. This is not
25 the tobacco industry. We rely on these drugs. And

0027

1 we want -- in fact, what we would really like to
2 see is the focus in terms of research and
3 development and the ways in which we talk about
4 drugs to be focused on the best value and the most
5 cost-effective drugs. So I think we're certainly
6 not looking to end the fine work that the
7 pharmaceutical companies do in developing drugs.

8 MR. KNOWLTON: Thank you for your
9 testimony, Marsha. For those who don't know,
10 Community Catalyst has been doing some very exciting
11 things. We're committed with another group and very
12 impressed with your group.

13 MS. HAMS: Thank you.

14 MR. KNOWLTON: I have a question for
15 you, Marsha. In fact, I was late for this meeting
16 because I had a meeting with some of your
17 colleagues. I have a question about what you think
18 is the tension on disclosure. There's a lot of --
19 there's been a lot of discussion about disclosure,
20 but it seems to me there's a tension in disclosure.
21 The tension is if you require universal disclosure,
22 you get a lot of noise, so consumers get -- I'm
23 taking the consumer side of this. How do they
24 differentiate? We require, for example, pretty
25 significant informed consent in this state. But how

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1 many of you really in an Emergency Room say, you
2 know, I don't want that done because bad things
3 might happen to me. You sign the informed consent
4 because your doctor puts his hand on your shoulder
5 and tells you it will be okay. So I wonder if this
6 sort of panacea that we think of disclosure doesn't
7 actually work against us and I wonder what your
8 reaction was to that.

9 MS. HAMS: Well, I think that -- I
10 certainly think it's a mixed message. I think it's
11 been very important that -- we support, for
12 instance, in state legislation a ban, not just
13 disclosure, that there be an outright ban, and in
14 the academic medical centers as well, on gifts.
15 Now, there are going to be exceptions obviously.
16 You have to define a gift. And so we think that
17 needs to be combined with disclosure of other
18 payments. I do think that you do get noise, and
19 that's something that, you know, for instance,

20 they're sorting out in Minnesota. I think that --
21 and sometimes it can be an excuse. So a physician
22 may list all of the contributions from a drug
23 company, and even someone that's listening to that
24 person give an educational presentation that has to
25 figure out what that means in terms of what they're

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1 hearing.

2 So the disclosure itself doesn't
3 answer that question. Sometimes it can be seen as
4 the answer when, in fact, what we really want to
5 move away from is the inappropriate payments and
6 really not be -- not supporting that. I think that
7 it's a -- it's complex. I think it's important
8 that the individual physician be named, because if
9 the information is only an aggregate, you can't make
10 the same kinds of analyses that Minnesota was able
11 to do, and I hope other states can do, in looking at
12 prescribing patterns in relation to the
13 inducements. You have to look at, you know, if
14 you're lumping research in there, that's -- you
15 know, we're not talking about legitimate research or
16 clinical research. So you have to take that into
17 account.

18 And I don't think it's likely going
19 to be a question of a patient looking at that and
20 saying to their doctor, why are you taking this
21 money, because I think a patient individually is in
22 a very vulnerable position, very unlikely to do
23 that. But patients as a -- looking at their
24 interests broadly I think can be supportive of
25 public policy that would control these kinds of

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1 influences, and it's not really a matter of their
2 individual action at the doctor's office I don't
3 think.

4 MR. KNOWLTON: Thank you.

5 DR. BLANKS: I'd like to make a --
6 if we're done -- are there any other questions from
7 the Committee? I'd like to make a little bit of a
8 schedule change here. The one person who did say
9 she has to leave right away I'd like to ask to speak
10 next. That's Dr. Lee-Ann VanHouten-Sauter,
11 Treasurer. Thank you.

12 MS. VAN HOUTEN-SAUTER: Good
13 morning. My name is Lee-Ann VanHouten-Sauter, and I
14 am from the New Jersey Association of Osteopathic
15 Physicians and Surgeons. And I'd like to thank you
16 for the opportunity to speak today. And I'm coming
17 from the physician perspective now, so we're getting
18 a little different view here. I'd love to see some
19 of the things that have happened and that were
20 mentioned by the two prior speakers, because as a
21 small-town physician in Williamstown, that's not
22 what my experience is. And I'm a family physician,
23 and I'm a second-generation family physician who
24 followed in my father's footsteps.

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Today I'd like to speak on three

1 areas of concerns that have been under the larger
2 umbrella of the physician compensation. And each of
3 these is an essential part to patient care, which I
4 think is my highest priority.

5 The first thing I'd like to address
6 are physician samples. Medication samples provided
7 to physicians offices have been a key element of
8 patient care as long as I've been in practice. As a
9 physician, my primary concern is working with my
10 patients to achieve the best results. In some cases
11 this means prescribing medications that are
12 prescriptions. Studies have shown that patient
13 compliance in taking medication as prescribed is
14 surprisingly low. One significant factor is the
15 cost of these medications.

16 The New Jersey Association of
17 Osteopathic Physicians and Surgeons has been
18 proactive in being an early supporter of the Rx4NJ
19 program that provides prescription medications at no
20 cost or low cost to eligible patients, and many of
21 our physician members provide program information to
22 patients in their offices for this program.

23 For patients, I believe some may not
24 have timely access to their prescribed medications
25 due to either the time of day or they may not get

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1 prescriptions filled because of the cost, and this
2 is where the potential for samples really comes in.
3 What happens in my office is a representative may
4 make an appointment and bring me lunch, yes. Wow,
5 Applebee's, you know, 8.95. You know, if I need to
6 disclose that, I guess I can. Do I think my patient
7 is not going to come to me or think I'm a bad doctor
8 because I'm eating lunch for 8.95 today? I don't
9 think so. Because they're coming to me because of
10 my medical judgments and how well, you know, I'm
11 treating them.

12 And a lot of my patients don't have
13 prescription coverage, so they wouldn't take any
14 medication if it wasn't for me being able to
15 contribute and give them almost all of their samples
16 for their diabetes. And the diabetic, remember,
17 could be on four medications in addition to their
18 underactive thyroid or their arthritis. So sample
19 medications is a big part of my practice, and I feel
20 that if I wasn't able to interact with the
21 representative and have them dropped to me, that
22 that would be a detriment to patient care, it would
23 not be an improvement in patient care.

24 When possible, we surely do try to
25 use generics. But remember, not all medications are

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1 a generic and not all generics are as effective as
2 each other or as effective as the brand medication.
3 And that, again, not having those samples to use

4 would again harm my patient, they wouldn't
5 necessarily help.

6 Very few, if any, generic medications
7 are ever even thought of to be left at my office by
8 any company, and so I don't have that choice. And
9 that's a major issue, too. Everybody wants us to
10 prescribe them, but not all generics are cheap.
11 There's generic equivalents they say out there, but
12 they aren't the equivalent, they aren't the same.
13 They're like another medication. So I feel that
14 that's a big issue that everybody needs to
15 understand when we, as a physician, are trying to
16 treat a patient, that surely we choose those when
17 possible, but they're not always the possible
18 choice.

19 The other reality here is that many
20 patients who have prescription coverage, and that's
21 probably close to 90 percent of people have some
22 type of prescription coverage here in New Jersey,
23 that those prescription drug benefits are really set
24 by the insurance formularies. So I can say I want
25 Drug A, but if that's not on the list, I don't get

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1 to let that patient have Drug A, because that gets
2 bounced back at the pharmacy with a fax to me or
3 call to me that says, Doctor, that person can't get
4 that medication, you have to choose something else.
5 So it's not as easy as it sounds that Company A
6 comes in and says, this is a great drug, you need to
7 use it, because that isn't always what the patient's
8 insurance is willing to pay for.

9 So I feel that these are some major
10 issues in sampling, that's why they're important and
11 why we should be allowed as physicians to continue
12 to receive those samples without being impeded by
13 outside forces saying that this is going to
14 influence me in a negative way. We're here to help
15 the patient, we're not here to harm them.

16 The next area I'd like to go over is
17 for clinical research. The subject of funding from
18 pharmaceutical companies to physicians for
19 professional services covers a broad range from
20 research to physician training. In the past several
21 months, Governor Corzine and members of the
22 New Jersey Legislature have been outspoken on the
23 benefits of increasing the private monies being used
24 for medical research rather than state funds. Most
25 of this has been part of a public discussion of

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1 stem-cell research after voters have failed to
2 approve that on the ballot referendum earlier this
3 month.

4 Moving forward, they have said that
5 industry and other private funding will be
6 essential. Many of the funded researchers will be
7 physicians inside and outside of pharmaceutical
8 companies and academia who will be compensated for

9 their professional contribution.

10 Just this summer, the New Jersey
11 Association of Osteopathic Physicians and Surgeons
12 has joined in a national research project on the
13 physician study of methicillin-resistant
14 Staphylococcus, otherwise known as MRSA to the
15 public. And this is where physicians here in
16 New Jersey have agreed to now look at patients in
17 their office and try to see if they have a wound, is
18 there a risk for this MRSA, and how will that be
19 treated.

20 Remember, this is important data that
21 we as physicians have entered into from an actual
22 privately funded company who hopefully will find a
23 medication to address this public, you know, health
24 issue right now. And that if, again, here in our
25 offices I wasn't allowed to do that because I'm

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1 being compensated less than one percent of my annual
2 revenue by that pharmacy's private-funded company,
3 you know, how does that impact on making my patient
4 better if I'm not allowed to be able to participate
5 in that. And I just feel that this would be an
6 issue.

7 If we believe that, indeed, the
8 research is genuine and evidence-based by protocol,
9 that recruitment of physicians with appropriate
10 training, as well as enough physicians in
11 relationship to the number of patients to facilitate
12 that study, would be a good thing to be permitted
13 without public disclosure.

14 And lastly, I'd like to discuss
15 continuing medical education. The activities that
16 provide physicians with the ability to improve
17 patient care is continuing medical education.
18 Stringent guidelines are already in place by the
19 Continuing Medical Education (CME) Accreditation
20 Council on Continuing Medical Education, as well as
21 pharmaceutical companies themselves. So the
22 Government's looking at this, the companies are
23 looking at this, and there have been new rules.

24 Again, I've been in practice since
25 1991, and I would say that in the last seven to

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1 eight years, the whole ball game has changed. And
2 that maybe when I first went into practice, yes,
3 there were things where you would be taken to a
4 continuing medical education afternoon and you would
5 also be treated to a round of golf. Today that
6 doesn't happen, or at least I have not had any
7 offers in the last seven years. You know, being
8 brought a box of tissues? Yes. You know what, that
9 sits in the waiting room for the patient to use. So
10 that's not something I take home to my family.

11 So I think that, you know, the
12 continuing medical education is a large part of how
13 we as physicians are able to gain new knowledge and

14 able to gain what's out there to continue to offer,
15 again, better patient care.

16 Remember in 2002, the State of
17 New Jersey formally recognized the value of
18 continuing medical education and stipulated that
19 50 hours of CME for physicians were required for
20 re-licensure per year. To achieve this requirement,
21 many physicians belong to associations and attend
22 professional conventions that offer such programs.

23 Most of these programs are funded in
24 part by pharmaceutical companies. Many of the
25 larger companies provide funding and adhere strictly

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1 to the new guidelines that have significantly
2 limited interaction with physicians. Our
3 association also adheres to these guidelines, and we
4 also sponsor many CME programs. It has become more
5 difficult for me, as somebody who organizes these,
6 to actually continue to find speakers who are
7 willing to do this at less of a fee.

8 CME grants provide a valuable and
9 important resource over and above the already
10 significant investment that physicians are making in
11 an effort to continually update the physicians on
12 the latest patient care.

13 In conclusion, as the Advisory panel
14 continues to deliberate on its issues in more
15 detail, I believe that it is extremely important for
16 the myriad of issues confronting physicians in
17 medical practice today to be raised in the context
18 of this discussion. There are many challenges that
19 a family doctor faces in the provision of patient
20 care. Increased regulation in this area would
21 create increased administrative burdens that would
22 extremely become problematical for me to deliver the
23 best patient care I can.

24 I appreciate this opportunity to
25 speak with you. And I'm happy to answer any

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1 questions.

2 MR. KNOWLTON: Thank you for your
3 testimony, Doctor. Did you -- in your experience,
4 since you've been in practice, did you find any --
5 you talked about all these things, did you find
6 any -- and both organizationally, at the
7 Association of Osteopathic Physicians and as a
8 private practitioner, have you found any gift
9 arrangement or compensation arrangement at any level
10 that you thought was inappropriate?

11 MS. VAN HOUTEN-SAUTER: Personally,
12 no, I never have. I just think -- again, maybe I
13 come from a different area or -- but again, in
14 these last seven or eight years, I have -- you
15 know, since the regulations have been put into
16 effect, you know, if bringing me lunch is an
17 offense, then yes. But I personally don't.

18 MR. KNOWLTON: I was asking your

19 perception.

20 MS. VAN HOUTEN-SAUTER: My perception
21 of being brought lunch from one of the local
22 establishments who then were also helping the public
23 because we're buying lunch from the local pizza
24 place is not offensive.

25 DR. BLANKS: Thank you.

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1 MS. VAN HOUTEN-SAUTER: Thank you.

2 MR. DE MARZO: Thank you.

3 DR. BLANKS: Jean.

4 DR. SILVER: Good morning. My name
5 is Jean Silver. As it says, I'm the Executive
6 Director of the National Physicians Alliance. And I
7 appreciate this opportunity to share our thoughts on
8 current and troubling financial entanglements
9 between the pharmaceutical industry and the medical
10 profession. On most points, I couldn't disagree
11 more with the previous speaker.

12 The National Physicians Alliance was
13 founded in 2005 with a mission to restore
14 physicians' primary commitment to the core values of
15 our profession: service, integrity, and advocacy.
16 We represent 10,000 physicians across medical
17 specialties and across the United States. Unlike
18 the vast majority of medical organizations, we
19 accept no money from pharmaceutical companies.

20 The National Physicians Alliance
21 believes that the public health is directly
22 threatened by commercial influences that now pervade
23 medical education and practice. It's become
24 increasingly difficult for physicians to find and
25 distinguish legitimate, evidence-based sources of

0041

1 medical information from sources either sponsored or
2 produced by companies with a financial stake in the
3 information presented. Pharmaceutical companies
4 have found myriad, powerful ways to market their
5 products and bias the medical literature. Our
6 members are especially concerned about the degree to
7 which our profession has become complicit in this
8 work.

9 Physicians have been incorporated
10 into the marketing machine as highly paid
11 consultants, as sponsored speakers, as willing
12 recipients of gifts and payments which do influence
13 their prescribing, and also as unwitting victims of
14 the sale of individual prescribing records for
15 commercial purposes.

16 The very distinction between
17 marketing and education has become hopelessly
18 blurred. Continuing medical education courses are
19 required for physicians to maintain their licenses
20 to practice medicine. They were established to
21 ensure ongoing clinical competency. Shockingly,
22 drug company sponsorship now accounts for more than
23 half of the CME courses that are available to

24 physicians. The industry spends well over a billion
25 dollars annually to develop CME courses for

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1 doctors.

2 While governing bodies have enacted
3 more rigorous guidelines on conflicts of interest in
4 these courses, we have doubts that the guidelines
5 will eliminate bias in course content. CME
6 providers certainly are aware of a company's profit
7 interest in supporting a course and may be
8 legitimately concerned about alienating their
9 sponsor. Even if the actual content of an
10 individual course is unbiased, the immense
11 dependency on industry dollars skews the entire
12 educational agenda for doctors towards the interests
13 of the pharmaceutical industry, interests inherently
14 focused on new drug treatments instead of important
15 life-style interventions or better prescribing of
16 time-tested, cost-effective, generic drug
17 therapies.

18 While it's true that doctors need to
19 be educated about new medicines, education should
20 come from qualified, independent scientists and
21 well-designed studies, not from propaganda prepared
22 by salespeople in the guise of education.

23 Consider the following common method
24 used by pharmaceutical companies to influence
25 prescribing under the guise of educational -- under

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1 the guise of education: anointing key opinion
2 leaders, physicians that are richly paid to lecture
3 to their peers about "best practices." These talks
4 often open with a quickly flashed slide that
5 discloses the fact but not the extent of the
6 speaker's financial relationships. Any omissions
7 are unknowable to the audience. Indeed, sometimes
8 it's not only the speaker who's being paid, but the
9 audience as well. One NPA member shamefully
10 recalled an all-expense two-day paid trip he took to
11 Las Vegas during his training, where he left with a
12 \$750 check for attending a four-hour consulting
13 session with twenty to thirty other doctors. And to
14 call this practice a "consulting service" is a real
15 stretch.

16 These marketing practices have proven
17 to be good investments for the industry, yet there's
18 no ethical place for the industry influence wrought
19 through gifts or sponsorship.

20 More importantly, the Journal of the
21 American Medical Association reviewing nearly thirty
22 studies concluded that gifts unquestionably
23 influence clinical decisions.

24 Industry gifts to physicians
25 encourage brand-name prescribing even where safe,

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1 effective, equivalent prescribing exists. This
2 leads to tremendous waste of taxpayer dollars in

3 Medicare and Medicaid and similarly contributes to
4 the rising cost of private health insurance. It
5 also leads doctors to become early adopters of new
6 drugs that lack long safety records, and that's a
7 risk to patients.

8 Pervasive industry incentives that
9 surround physicians are undermining medical
10 integrity and trust in the profession, and there is
11 a need for State involvement.

12 The pharmaceutical industry has
13 cultivated this marketing relationship over so many
14 years and has embedded it so deeply in the medical
15 profession that volunteer efforts are not working.
16 The public should not have to wait for the medical
17 profession to clean its own house, which could take
18 decades in the absence of regulation.

19 A recent survey in the New England
20 Journal of Medicine reported that 94 percent of
21 physicians, almost all of them, still accept
22 payments or gifts, Kleenex and lunch and more, from
23 the pharmaceutical industry, despite the voluntary
24 guidelines created in partnership between PhRMA and
25 the AMA.

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1 The state licensure process has a
2 responsibility to the public to ensure that patients
3 are acting primarily on behalf of -- that
4 physicians are acting primarily on behalf of their
5 patients. This is not something that patients can
6 reasonably judge from everyday office encounters
7 with their doctors, particularly when the profession
8 is awash in these gifts, incentives,
9 industry-sponsored training, and other conflicts of
10 interest.

11 The case of prescription datamining I
12 think is particularly apt here. The American
13 Medical Association earns over \$44 million annually
14 from the sale of its Physician Masterfile data, data
15 which is coordinated with pharmacy records and sold
16 to pharmaceutical companies as a tool for targeted
17 brand marketing to individual physicians. A study
18 from the Kaiser Family Foundation found that nearly
19 three-quarters of physicians disapprove of this
20 practice when they learn about it.

21 We do have some proposals for
22 reform. The National Physicians Alliance would like
23 to see a formal ban on industry gifts to physicians,
24 and even small gifts, even pens and trinkets which
25 also have been shown repeatedly and convincingly to

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1 influence decision-making.

2 As a second-best option if a clear
3 and complete ban is not supported, then we would
4 like to see mandatory disclosure by industry of
5 gifts to physicians, by name, in a public registry,
6 as is being proposed in the District of Columbia and
7 at the Federal level with the Physician Payments

8 Sunshine Act.

9 And I agree with what you were
10 highlighting before, that disclosure of conflicts of
11 interest doesn't eliminate conflicts of interest at
12 all, it just sheds light on the problem, it just
13 provides data, and that data might be more useful at
14 a collective level from the perspective of public
15 payers than at the level of individual patient. I
16 mean, if you see that your doctor is -- you know,
17 90 percent of the income is coming from one company,
18 that might raise a red flag to a patient. But
19 actually these laws wouldn't even give you that data
20 because you wouldn't know total income. But say
21 whatever, \$3 million a year, that might raise a red
22 flag.

23 And the responsibility for this
24 disclosure if this were the way you went should fall
25 on industry. They already track all this data.

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1 They already have it. And physicians are not in a
2 position necessarily to always know where drug
3 company funding exists.

4 The NPA also proposes a new
5 requirement that a majority of CME credits earned
6 for license renewal come from nonindustry sources.

7 We'd like to see the creation of
8 Class A and Class B CME credits where Class A is
9 free of industry funding and Class B isn't.

10 CME providers should be required to
11 denote which class their course falls under, which
12 would make it easy for physicians to know and comply
13 with the state regulation.

14 New Jersey requires physicians to
15 earn 100 CME credits per two-year license-renewal
16 cycle. We consulted with a CME provider in the
17 northeast who does not take industry funding and his
18 estimate of the cost per credit was five to ten
19 dollars. At the upper extreme, our proposed
20 requirement would translate into roughly a \$250
21 out-of-pocket expense per physician per year, a
22 professional business deduction at that.

23 Other proposals include the
24 development and mandatory dissemination with license
25 renewals of a booklet outlining the scope and

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1 consequences of pharmaceutical marketing strategies,
2 with a bibliography of independent sources of
3 medical education, such as the Drug Effectiveness
4 Review Project Reports, the Independent Drug
5 Information Service, the Medical Letter, the kind of
6 references that you'll find on that PharmedOut site
7 that there are alternatives. Ads, and this goes to
8 the curriculum question, like media literacy for
9 kids, how you read these ads when they're coming at
10 you all the time.

11 Last, we would very much like to see
12 the Board adopt an opt-in requirement for the sale

13 of prescribing records for marketing purposes, and
14 that such an opt-in option should appear on all
15 license applications and license renewal forms, as
16 is the case in Maine and Vermont. I mean, NPA would
17 prefer to see a ban on the sale of this data, but
18 short of that, that would be a step in the right
19 direction would be an opt-in rather than an
20 opt-out.

21 In closing, the National Physicians
22 Alliance welcomes the Attorney General's attention
23 to conflicts of interest within the profession and
24 to the undue influence of pharmaceutical marketing
25 strategies. Physicians need better laws and rules

0049

1 on CME to help us restore the integrity of the
2 profession from within. We look forward to working
3 with you and others on these issues. The NPA is
4 eager to help achieve a safe, affordable, and
5 effective health care system for all patients.

6 Thank you.

7 MR. DE MARZO: I just have a
8 question. You spoke about propaganda. Would you
9 concede that there are legitimate educational
10 programs necessary, if a manufacturer brings a new
11 device to the market or if a new drug is brought to
12 the market, would you concede that there is a
13 legitimate purpose to such a session to educate a
14 physician about that? And if you do, how do you
15 distinguish between that and propaganda as you put
16 it?

17 DR. SILVER: I think that to a
18 statistician, an epidemiologist, somebody skilled to
19 look at these studies carefully, the difference
20 between a well-designed study and a very poorly
21 designed study is clear, and there are common tricks
22 that are used and worked through. So typically,
23 even things that are poor studies are packaged up to
24 look like good studies. And what's presented in the
25 typical rep encounter can be very skewed. And

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1 physicians don't have the time, a lot of them don't
2 have that background to sit there and piece apart
3 the methodology and challenge it. They're shown
4 something, they're shown a finding. There's a lot
5 of inundation.

6 Of course, when there's a new device,
7 physicians need to learn how to use it, how it
8 compares to other devices. Of course that education
9 needs to happen. But I'm very concerned about the
10 degree to which the whole notion of education has
11 been appropriated by the marketing arm of these
12 pharmaceutical companies. And I don't have a
13 simple, clear, one-line answer about, oh, well, this
14 is how you tell the difference. But we've got to
15 start telling the difference and we've got to start
16 helping physicians learn how to recognize it.

17 I mean, the sales reps -- the sales

18 reps present -- the pharmaceutical industry
19 presents their marketing teams as physician
20 educators, and they are literally becoming that.
21 They're dominating the educational system from
22 medical school all the way through continuing
23 medical education. We're now being educated by
24 sales reps with minimal scientific training.
25 They're recruited for their charisma, their

0051

1 persuasive abilities. They're not recruited because
2 they're great scientific thinkers or even trained at
3 all in science. So it's of great concern.

4 DR. BLANKS: Go ahead, Doctor.

5 DR. CHEEMA: You mentioned about the
6 CME, that industry spends about \$1 billion in CME
7 courses. And you also suggested that that should be
8 stopped.

9 DR. SILVER: No, I didn't. No. My
10 proposal was that the Board require that a majority
11 of CME credits that a physician has to earn for that
12 renewal, a majority, 51 percent, come from
13 nonindustry sources. I'm trying -- my proposal is
14 intended to inject some balance so that it's not all
15 coming from materials produced by people with a
16 financial stake in what you draw from what they say.

17 DR. CHEEMA: But you mentioned
18 50 percent come from the industry. Didn't you
19 mention that 50 percent of the money spent on CME is
20 by the industry, which is close to 500 million? If
21 that is eliminated, where is the money coming from,
22 will come from?

23 DR. SILVER: Oh, it's not -- I don't
24 imagine that it would be eliminated at all, but I do
25 think that such a regulation would create a demand

0052

1 for new markets, new products, hospitals. The
2 structure is already there for hospitals to offer
3 CME. You know, if you're an accredited institution,
4 you can offer CME on any topic you want. We might
5 see, in the case of a disease like diabetes, some
6 courses that are on things that are less focused,
7 you know, more on prevention, health maintenance,
8 less on the newest med, and that balance might be
9 very good for patients if the doctors got that
10 education. But when the whole agenda is driven by
11 sponsors of products, it skews the whole menu of
12 what's available.

13 DR. BLANKS: How do you evaluate the
14 third-party CME sponsor who receives money from an
15 unrestricted educational grant from the industry and
16 maybe -- and then acts as a firewall to present an
17 objective balanced course? I mean, when you say CME
18 that's not industry-sponsored, do you mean not
19 industry-sponsored directly, or do you mean not
20 industry-sponsored in that it's based on an
21 unrestricted educational grant to a third party?

22 DR. SILVER: It's a great question.

23 And I don't have a straight answer for it. Clearly
24 regulation has to be written so everybody just
25 doesn't quickly create a front shop to channel the
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1 CME course work through. Right now many of the CME
2 generating companies are -- you know, are
3 maintained by pharmaceutical companies. That's just
4 sort of outsourced to separate companies that
5 generate CME. And I certainly would consider that
6 industry-funded. I mean, maybe, you know, whether
7 the company would survive without industry funding
8 might be a measure of whether they're independent or
9 not. I don't know. But I don't have a detailed
10 proposal. I would be happy to work with you more on
11 it.

12 DR. BLANKS: And the place of
13 professional societies who offer CME, is there --
14 they're also a third party that accepts an
15 unrestricted educational grant, but they're also
16 more the professional guild kind of organization.

17 DR. SILVER: It is so pervasive and
18 it's in all these different places, and the proposal
19 is designed to create pressure for delusions to this
20 extraordinary and universal dependency.

21 DR. BLANKS: Thank you.

22 MS. JOYCE: Samples, what's the
23 position of the organization with respect to the
24 provision of samples to physicians?

25 DR. SILVER: I think samples are
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1 generally described by proponents as, you know, a
2 great way to get important meds to poor people. And
3 that's not really their purpose. Their purpose is
4 to get physicians into the habit of prescribing
5 those newest -- they don't sample anything but the
6 most expensive newest meds. And they don't sample
7 physicians who are just serving in very poor inner
8 city areas where everybody's on Medicaid and they're
9 not going to get those meds anyway. Those docs
10 don't get an Applebee's lunch. They don't get any
11 samples at all.

12 The samples are designed because it
13 gives the physician a convenient way to hand a
14 patient something. If a patient started on a med
15 and they don't have a bad reaction to it, they're
16 very unlikely to be changed off that med. So if
17 these are life-style meds, ones patients are going
18 to be on many years for conditions, it's of great
19 value to the company to have that first trial of a
20 med be their new one. And so that's the purpose,
21 that's the real purpose of samples.

22 There are, of course, times when the
23 sample is useful to somebody who couldn't otherwise
24 get it. I completely concede that. I think that's
25 a minority of the situation. This is the most
0055

1 effective tool that the drug reps have. It's

2 the -- if they stopped sampling, a lot of
3 physicians wouldn't have so much interest in meeting
4 with them at all. It gives the physician a
5 mechanism to provide a gift to the patient which
6 builds goodwill. It makes patients feel good to get
7 something for free. It helps that relationship.
8 It's an extremely effective tool, and it starts
9 patients on a lot of new meds without long safety
10 records, and it gets -- it's a convenient thing
11 that's manipulative and effective and portrayed as
12 something that it's not.

13 MS. JOYCE: So the organization's
14 position would be that it ought not to be allowed?

15 DR. SILVER: I can't say that we
16 would call for a ban on all samples, but we think
17 that samples need to be looked at very critically
18 and recognized for the marketing tools that they
19 are.

20 MS. JOYCE: Thank you.

21 MR. KNOWLTON: Thank you for your
22 testimony, Doctor. What -- I didn't catch at the
23 start, are we going to get your testimony? Did you
24 hand it out to us?

25 DR. SILVER: I don't know if I have

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1 enough copies with me, but I can certainly get it to
2 anybody.

3 MR. KNOWLTON: And I didn't catch at
4 the beginning, something about your organization.
5 Would you -- I'm not familiar with your
6 organization.

7 DR. SILVER: We're a new
8 organization. We're a multispecialty organization
9 founded in 2005, founded by former leaders of the
10 American Medical Student Association, which has been
11 around for a half century doing good work. Those
12 leaders felt that there was not a -- that there was
13 a void in organized medicine, that people had their
14 specialty societies they could be a part of, but in
15 terms of a multispecialty physician organization
16 whose mission was patient centered advocacy rather
17 than sort of a trade perspective or a guild
18 perspective in the interest of physicians, that that
19 really wasn't out there for a multi-issue
20 organization. So that was the motivation for the
21 founding of the NPA.

22 MR. KNOWLTON: And you're national in
23 scope based where?

24 DR. SILVER: We're based in Virginia.

25 MR. KNOWLTON: National in scope?

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1 DR. SILVER: National in scope,
2 yeah.

3 MS. WOOD: Good morning. My name is
4 Leslie Wood, and I'm a State Policy Director with
5 the Pharmaceutical Research and Manufacturers of
6 America. Thank you, Committee members, for allowing

7 us to come in today.

8 Our companies are the research-based
9 companies who research and develop new medicines
10 and, after receiving Food and Drug Administration
11 approval, bring these meds to patients. Therefore,
12 we are extremely interested in making sure that
13 physicians have the correct information about our
14 medicines before prescribing to patients.

15 Today I'd like to discuss federal
16 laws that are currently in place regulating our
17 industry. As you know, our industry is the most
18 highly regulated business community out there. And
19 I'd also like to talk to you about the benefits of
20 communications between pharmaceutical companies and
21 physicians and other health care prescribers.

22 I'd first like to mention that both
23 brand and generic drugs, as well as cost associated
24 with running pharmacies per the centers of Medicare
25 and Medicaid services actually comprise 10 percent

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1 of the health care dollar. To put that in context
2 for you, about 7 percent of the health care dollar
3 goes toward paying administration expenses
4 associated with running the health care industry and
5 treating patients nationally.

6 I'd also like to mention that we
7 believe that relationships with physicians are
8 good. We believe as the developers of medicine who
9 know their medicines best that we can provide the
10 best education. We also believe that we need
11 physician help in translating the chemical of the
12 prescription medicine so that we can make sure that
13 we know the benefits and the risks of medicines
14 before distributing them to patients.

15 I'd also like to mention that in
16 New Jersey, if a physician does prescribe a brand
17 name drug and there's a generic available, the
18 pharmacist must dispense the generics. We support
19 the use of generic drugs. We know that we have
20 patent protection for a certain number of years
21 because of the amount of money we put into research
22 and development, but at the point of expiration, we
23 understand that generics are used, and we support
24 that.

25 I'd first like to talk about the Food

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1 and Drug Administration and how they regulate our
2 industry. They oversee all information and
3 materials distributed about a medicine. These
4 materials are developed by health care
5 professionals, medical experts, pharmacists and
6 scientists. And materials for new drugs are
7 submitted to the FDA before going to physicians.
8 I'd like to emphasize that company representatives
9 cannot talk about information not contained in the
10 Food and Drug Administration's approved labeling of
11 the drug. Doing so could deem the drug misbranded

12 under the Food and Drug Cosmetic Act, and that can
13 result in penalties. For example, a \$1,000 penalty,
14 a year of imprisonment. Repeat offenders get fines
15 up to \$10,000 and three years of imprisonment.

16 Also, in 2008, there's a new law that
17 was just passed, the Food and Drug Administration
18 Amendments Act, and that will provide for the
19 screening of all new television commercials, as well
20 as put new requirements on print ads and other
21 advertisements that patients might see.

22 In addition to the FDA's oversight,
23 the Department of Justice has Social Security
24 Administration anti-kickback laws. Quid pro quos
25 between physicians and pharmaceutical companies are

0060

1 not allowed. Penalties can include \$500,000 per
2 organization and I believe \$250,000 per individual.
3 There's also five years of a prison term that can be
4 associated with that. Violators can also be
5 excluded from the Federal Medicare and Medicaid
6 program participation.

7 In addition, there's the False Claims
8 Act, which provides -- which prohibits knowingly
9 presenting the Government with a fraudulent claim
10 for payment or approval. This can be used in
11 conjunction with the anti-kickback law to penalize
12 any violators of this Act. Penalties include civil
13 damages, as well as compensating whistle blowers.

14 In addition to these laws, in 2003
15 the Department of Health and Human Services, Office
16 of Inspector General issued guidelines to
17 pharmaceutical companies on how to comply with these
18 laws. Key themes include that interaction should be
19 focused on information about medicines to health
20 care professionals. Gifts and meals may be provided
21 as long as they are in limited value and under
22 limited circumstances. Consulting arrangements with
23 providers to perform bona fide services may not be
24 linked to prescribing practices. Payment for bona
25 fide services should be fair market value for the

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1 services rendered.

2 The OAG also provides guidance for
3 constructing appropriate compliance programs at the
4 company level.

5 And I also brought with me today,
6 which I can leave behind with you, the PhRMA Code on
7 Interactions with Health Care Professionals. The
8 CEOs of our member companies have adopted this Code,
9 and members also -- member companies also have
10 their own compliance programs in place.

11 I know we've heard a couple stories
12 this morning about giving extravagant gifts, such as
13 travel, entertainment, things of this nature. Under
14 our Code, that's just not allowed. We want our --
15 our companies want to know if there's a violation
16 out there, if there's someone out there violating

17 this portion of our Code. Our CEOs want to know
18 about that. It's just unacceptable. Physicians may
19 not have a guest at health care presentations. But
20 as I mentioned, in accordance with the OAG
21 guidelines, gifts primarily for the benefit of the
22 patient may be provided if not of substantial value,
23 which is considered to be \$100 or less.

24 Interactions are focused on the
25 timely scientific and education -- delivery of

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1 scientific and education materials that give a
2 balanced picture of the benefits and the risks of
3 pharmaceuticals. For example, a manufacturer might
4 hold a -- provide a medical expert to be available
5 to give a presentation to peer physicians regarding
6 a medicine. Also, perhaps a medical reference book
7 or patient brochures.

8 Now that I've talked to you a little
9 bit about some of the federal regulations in place
10 that are governing our industry, I'd also like to
11 talk to you about the great benefits of our industry
12 in providing information to both patients and
13 physicians.

14 Pharmaceutical companies, as I
15 mentioned, are the experts on their medicines. They
16 can provide updates to physicians, the latest
17 information about a prescription medicine, best
18 practices, and how to improve patient care.
19 Patients are educated through direct-to-consumer
20 advertisements, but this leaves the diagnosing and
21 prescribing power to the physician, who is a learned
22 intermediary, who is a licensed professional, and
23 who also has ethics training.

24 Direct-to-consumer advertising
25 encourages patients to talk to their physicians

0063

1 about symptoms which can lead to early diagnosis of
2 conditions that are often undertreated and often
3 underdiagnosed.

4 For example, Prevention Magazine in
5 its 2007 survey said that an estimated 29 million
6 Americans first talked to their physician about a
7 medical condition that they hadn't before after
8 receiving a direct-to-consumer advertisement.

9 According to a Harvard University and
10 Mass General Hospital study on direct-to-consumer
11 advertising, patients, after they've seen an ad,
12 25 percent of them received a new diagnosis. Half
13 of these diagnoses are priority, undertreated
14 diagnoses per the Institute of Medicine, including
15 high cholesterol, hypertension, diabetes and
16 depression. This is good news considering that more
17 than 58 million Americans suffer from high blood
18 pressure, yet 30 percent of these patients do not
19 know that they have it and are not being treated.

20 I would like to emphasize that asking
21 a physician about a medicine does not mean that the

22 patient comes away with the medicine. Studies show
23 that physicians first consider life-style changes
24 before prescribing a medicine. Also, Prevention
25 Magazine said that patients coming in after seeing a

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1 direct-to-consumer ad at their next visit,
2 73 percent just talked about the medicine, whereas
3 25 percent actually did ask for the medicine.
4 However, an FDA survey found that physicians do not
5 feel pressured to prescribe medications just because
6 their patient asked for it.

7 I'd also like to mention that
8 direct-to-consumer advertising can also increase
9 compliance. 75 percent of arthritis patients who've
10 seen an ad are more likely to comply with their med,
11 as well as nearly 40 percent of patients being
12 treated for depression.

13 In closing, pharmaceutical marketing
14 provides great value to physicians and their
15 patients, but it's supplying information that
16 informs conversations in the patient and physician
17 relationship. To ensure that individual patients
18 receive the best treatment, the U.S. Government does
19 highly regulate our industry to prevent quid pro
20 quos and to preserve the delicate nature of this
21 relationship.

22 Also, there are new regulations, as I
23 mentioned, that will be going into effect for print
24 ads and patient acts.

25 Thank you very much. I'd be happy to

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1 take any of your questions. Yes, sir.

2 DR. CHEEMA: You mentioned that you
3 have the booklet in front of you, the PhRMA Code.

4 MS. WOOD: Sure. Let me pass them
5 out in case there's any questions while I'm up
6 here. Is that all right?

7 MS. JOYCE: We have -- actually have
8 that.

9 MS. WOOD: You have that? I'm
10 sorry. I also brought a list of the rules and
11 regulations and the appropriate cites in case that
12 would be helpful.

13 MS. JOYCE: I think we have that as
14 well.

15 MS. WOOD: Yes, sir.

16 DR. CHEEMA: You mentioned about the
17 PhRMA Code and the laws and fines and prosecution.
18 Do you have any information at present how many
19 pharmaceutical executives and doctors are in jail
20 not following these Codes?

21 MS. WOOD: I don't have information
22 about people in jail. However, there have been some
23 recent settlements in the news. And I can't comment
24 on particular cases 'cause I don't work for the
25 individual companies, I don't know the particulars

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1 of the settlements, but we do -- you might have
2 heard of something up in Boston recently. And we
3 believe that's the, you know, regulations at work.

4 DR. CHEEMA: Second question. Do you
5 think the pharmaceutical industry and the doctors
6 are following these Codes?

7 MS. WOOD: When you say quotes, what
8 do you mean?

9 MS. JOYCE: Codes. Following the
10 Code.

11 MS. WOOD: Yes, I do. And as I
12 mentioned, our companies want to know about any sort
13 of violation that could be out there.

14 We also do have something on PhRMA on
15 our website. If anyone has a complaint about
16 direct-to-consumer advertisement, there's an avenue
17 to bring that in. And as I mentioned, the FDA will
18 be receiving additional funding this year to go
19 ahead and review all advertisements that are put on
20 TV. Yes.

21 DR. BLANKS: Are you aware of what
22 percentage of pharmaceutical companies that market
23 in the United States are members of your
24 organization?

25 MS. WOOD: As far as the percentage

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1 goes, last year \$55 billion was spent on research
2 and development, and our company spent \$43 billion
3 on research and development. And as I said, we're
4 the research-based companies, not the generic
5 companies. So about 80 percent of the funding for
6 R&D comes from our companies.

7 DR. BLANKS: So there are companies
8 that do R&D and that do marketing of brand name
9 pharmaceuticals that are not members of your
10 organization?

11 MS. WOOD: There are a few
12 organizations, yes, ma'am. But again, those
13 companies also have the OIG guidelines that they
14 need to comply with and all the federal laws and
15 regulations.

16 DR. BLANKS: Just not your voluntary
17 Code, the PhRMA Code?

18 MS. WOOD: They may follow something
19 similar, and they have to have their own compliance
20 program in place as well.

21 DR. BLANKS: Thank you very much.

22 MS. WOOD: Okay. Thank you.

23 DR. BLANKS: I think we'd like to
24 just take a five-minute break, walk around a little
25 bit. And if you have not signed in that you're

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1 attending today, we appreciate you signing in in the
2 front here.

3 We'll be back in five minutes. Thank
4 you.

5 (A brief recess is taken.)

6 DR. BLANKS: All right. We have a
7 couple of little changes in the order. The next
8 speaker is going to be Dennis Marco from Northern
9 New Jersey Chapter of Leukemia and Lymphoma Society.

10 MR. MARCO: Thank you, Dr. Blanks and
11 members of the Task Force.

12 My name is Dennis Marco. I'm here
13 today on behalf of the Leukemia and Lymphoma
14 Society. I currently serve on the Northern
15 New Jersey Chapter Board of Trustees. I'm also on
16 the National Board of the Leukemia and Lymphoma
17 Society, and I'm also the Chairman of the Republic
18 Policy Committee.

19 The Society is now the third largest
20 voluntary health agency in the nation with revenues
21 this year of over \$270 million. The Society funds a
22 diversified peer review medical research program,
23 patient services programs, in its sixty-six chapters
24 across the United States and Canada and advocacy
25 programs at the Federal and State levels, the vast
0069

1 majority of revenues derived from events that
2 include marathons, walks, and individual donations.

3 Pharmaceutical funding last year made
4 up less than 4 percent of our organization's budget
5 at roughly \$10 million. Of that PhRMA funding,
6 virtually all of it went to support the Society's
7 patient services programs, not to researchers and
8 not to doctors. Furthermore, the Society has in
9 place a number of safeguards to ensure the
10 independence, integrity and credibility of its
11 communications with patients.

12 Industry funding may be utilized in
13 three Society areas with specific guidelines in
14 each.

15 First, sponsors can support specific
16 patient services projects, such as a webcast,
17 teleconference, publications, or other patient
18 programs. In those instances, sponsors may only
19 provide funding as part of an unrestricted
20 educational grant. They have no input on the format
21 or composition of the program. In essence, the
22 sponsor sibling gets their sponsor on the program
23 announcement.

24 Second, sponsors can provide funding
25 for the Society's recently launched co-pay program
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1 that assists patients with drug purchasing.
2 Industry funding for this program can be fee
3 specific, for example, leukemia, lymphoma, myeloma,
4 but cannot be used to support specific drugs. And
5 furthermore, sponsors of the copayment fund are not
6 made public.

7 Finally, the Society has received
8 small industry grants, fifty to seventy-five
9 thousand annually to support its Mission Day in
10 Washington, D.C., in which patients advocate for

11 increased cancer research funding with their
12 Congressional representatives. Again,
13 pharmaceutical industry grants are made on an
14 unrestrictive basis, and sponsors have no input on
15 the format or composition of the program.

16 We respectfully request that the Task
17 Force take into consideration how the Society and
18 other nonprofit health care voluntary organizations
19 manage these types of positive programs and
20 understand the value and positive impact these
21 programs have on our patients.

22 Thank you. And if you have any
23 questions, I'll be happy to answer them.

24 DR. BLANKS: Okay.

25 MR. DE MARZO: Thank you.

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1 MR. MARCO: Thank you very much.

2 DR. BLANKS: Okay. Could I ask one
3 more nonprofit to speak, Meryl Stone from the CARES
4 Foundation, and then we'll get back on our schedule.

5 MS. STONE: Thank you for the
6 opportunity to speak today to this public conference
7 of the Office of Attorney General.

8 My name is Meryl Stone, and I'm here
9 to represent the CARES Foundation, headquartered in
10 Union, New Jersey. CARES Foundation is a 501(c)(3)
11 nonprofit organization committed to education and
12 research for Congenital Adrenal Hyperplasia while
13 providing the resources and latest information
14 available for managing life with CAH. CARES
15 Foundation is the only organization in the U.S. that
16 is dedicated to the support of Congenital Adrenal
17 Hyperplasia.

18 Congenital Adrenal Hyperplasia is a
19 family of inherited disorders affecting the adrenal
20 gland that affects males and females in equal
21 numbers. Classical CAH must be detected at birth to
22 avoid adrenal crisis. Most states, including
23 New Jersey, screen for this disease. CARES
24 Foundation is a strong advocate of newborn
25 screening, and we have been instrumental in getting

0072

1 newborn screening legislation passed in many states
2 across the country, including New Jersey.

3 The classical form of the disease
4 impacts a relatively small proportion of our
5 population, approximately one of every ten to
6 fifteen thousand Americans. However, to those
7 afflicted with CAH, the impacts can be
8 life-threatening. The milder form, called
9 Non-classical CAH (NCAH), may cause symptoms at any
10 time from infancy through adulthood. NCAH is a much
11 more common disorder than the Classical CAH and
12 affects some ethnic populations more than others.
13 Fortunately, CAH can be managed with medication and,
14 with adequate care, affected individuals can go on
15 to live normal lives.

16 I realize that today's meeting is to
17 take testimony from groups concerning the issue of
18 physician compensation in several forms. I also
19 wanted to use this opportunity to talk about our
20 interaction with the pharmaceutical industry.

21 The work of the CARES Foundation is
22 made possible in large part because of our
23 collaborations with pharmaceutical companies,
24 laboratories and laboratory equipment companies.
25 They have been involved in our work since nearly our
0073

1 inception and have been very responsive to the needs
2 of our community. I say that having just come off
3 our organization's annual conference in Los Angeles
4 this past weekend.

5 It would be impossible to put on such
6 a conference without the support of these
7 organizations. We assembled leading researchers
8 from academia and industry in one place to talk
9 about the latest treatments and breakthroughs in
10 research to treat this condition. Our conference
11 brought together the best and the brightest in the
12 medical field to help patients and their families
13 manage their disease. Without the support of the
14 private industry, in large part the pharmaceutical
15 community, this annual conference would simply not
16 happen.

17 The conference brings together over
18 three hundred patients and their families with
19 leading physicians and CAH researchers each year.
20 For many families, this is the first time they are
21 meeting with others afflicted with this adrenal
22 disorder. They're often overwhelmed with the amount
23 of medical information they receive and they're
24 extremely grateful that this opportunity exists for
25 them.

0074

1 CARES Foundation is highly dependent
2 on donations from the pharmaceutical and laboratory
3 equipment industries. Approximately 15 percent of
4 our total budget comes from donations from these
5 companies themselves and their foundations.
6 Medicines made to diagnose and treat CAH do not
7 impact a large number of Americans or people
8 worldwide. In fact, they are probably a good
9 example of being a classic orphan drug, drugs that
10 serve a small population of individuals, but the
11 industry has supported us much the same, even though
12 this is not a disease impacting millions, such as
13 cancer, diabetes, heart disease or others.

14 CARES Foundation and our members have
15 also benefited mightily from the industry's outreach
16 in recent years in the Rx4NJ program. Rx4NJ, as you
17 may know. Is a program serving as an umbrella for a
18 multitude of patient assistance programs designed to
19 get medicines to those individuals that might not be
20 able to afford them. Rx4NJ has served over 250,000

21 New Jerseyans since its inception at the beginning
22 of 2005. It also proved to be an effective test
23 case for the now national Partnership for
24 Prescription Assistance Program.

25 I wanted to use today's opportunity
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1 to talk about our interactions with the
2 pharmaceutical, laboratory and lab equipment
3 companies. CARES believes that while there may have
4 been past abuses in the area of physician gifts and
5 compensation, that enough safeguards now exist. In
6 our seven years of existence, we have never
7 encountered any abuses. We would hope that the
8 beneficial relationship we enjoy with these
9 companies, many of whom are based in our own state
10 of New Jersey, will not be imperiled with the
11 possibility of needless regulation, which would put
12 small health care nonprofit organizations such as
13 ours out of business.

14 I thank you for the opportunity to
15 present these comments.

16 MS. JOYCE: A conference such as
17 you've described, would you be getting support from
18 multiple companies at the same time, or is it
19 generally funded by one industry representative?

20 MS. STONE: We have many different
21 companies that support us. I don't know, we must
22 have had about eight or nine different companies.
23 And then we get a large part of our funding just
24 from our own fund-raising efforts and donations.
25 It's not all, you know, pharmaceutical by any means,

0076
1 I wish.

2 DR. CHEEMA: The funding you get from
3 the pharmaceutical company are restricted or
4 unrestricted?

5 MS. STONE: They are unrestricted.
6 They're only for the use of the conference, but they
7 don't in any way talk about content or anything like
8 that.

9 DR. BLANKS: This is not a continuing
10 medical education conference for physicians, this is
11 researchers coming together with patients?

12 MS. STONE: Correct.

13 DR. BLANKS: Is there any conflict of
14 interest policy that the researchers have to
15 disclose during their presentation, what their
16 relationship with the industry that may be
17 sponsoring the conference is?

18 MS. STONE: I'm not sure. I would
19 have to get back to you on that.

20 DR. BLANKS: Thank you.

21 MS. STONE: Thank you.

22 DR. BLANKS: Next we are having
23 Mr. Bill Healey who's speaking for Tom Tremble from
24 AdvaMed. We're going to look at the device
25 industry.

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1 MR. HEALEY: Dr. Blanks, members of
2 the Committee, thank you very much and thank you for
3 welcoming this pinch hitter. Because of a family
4 emergency, Mr. Tremble needed to remain in
5 Washington. So I will be delivering the statement
6 of the Advanced Medical Technology Association.

7 AdvaMed appreciates the interest of
8 the Attorney General and the Board of Medical
9 Examiners in ensuring that compensation from
10 manufacturers to health care providers doesn't
11 inappropriately influence medical decisions.

12 AdvaMed member companies produce the
13 medical devices, diagnostic products and health
14 information systems that are transforming health
15 care through earlier disease detection, less
16 invasive procedures and more effective treatments.
17 The members of AdvaMed produce nearing 90 percent of
18 the health care technology purchased annually in the
19 United States and more than 50 percent purchased
20 annually around the world. AdvaMed's members range
21 from the largest to the smallest innovators and
22 technology companies.

23 AdvaMed member companies rely on
24 regular interaction with health care professionals
25 to assist with developing new products, including

0078

1 orthopedic implants, defibrillators, pumps,
2 cardiovascular stents, and other devices for
3 diagnosing threatening diseases. Collaboration, let
4 me under score this, collaboration between
5 manufacturers and health care professionals is
6 essential to the medical device development
7 process.

8 Devices are different. Advisory
9 Committee members need to understand that medical
10 devices are different from drugs. While that may
11 seem obvious, there's often an urge to find a "one
12 size fits all" solution. This will not work for
13 this issue since medical devices are very different
14 from drugs in the way they are developed and the way
15 that health care providers learn how to use them.

16 Let me give a few examples. Drugs
17 are discovered. Devices are developed. Physicians
18 often play a key role in the identification and
19 development of new medical technologies. Unlike
20 drugs primarily developed in a laboratory, the
21 innovative nature of medical devices involves
22 ongoing collaboration with providers. Manufacturers
23 utilize physician feedback to continually improve
24 these devices. That makes it easier to administer
25 and makes them more effective for patients.

0079

1 Physician collaboration has led to
2 ground-breaking advances in patient care, such as
3 improved total joint replacement surgeries through
4 the development of new prosthetic knees and other

5 medical equipment, development of a catheter which
6 revolutionized the removal of embolisms, improved
7 care for patients with bone and soft-tissue cancer
8 by developing a customized bone replacement system.

9 Physician training is critical for
10 the safe and effective use of many devices. These
11 devices have become much more sophisticated. They
12 require that physicians are provided with
13 specialized education and training on using and in
14 some cases implanting a device. In fact, for some
15 devices, the FDA requires that manufacturers provide
16 training to physicians as part of the clearance to
17 market.

18 Let me address AdvaMed's Code of
19 Ethics. AdvaMed has a strong commitment to ethical
20 arrangements in the industry. We have developed and
21 aggressively market a strong industry Code of
22 Ethics. It may be helpful if I can describe
23 AdvaMed's Code of Ethics on Interactions with Health
24 Care Professionals. This is a voluntary code of
25 conduct providing device manufacturers with guidance

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1 as to appropriate relationships with health care
2 providers. AdvaMed's Code was adopted by the Board
3 of Directors in 2004 and has since been gaining
4 widespread industry acceptance. AdvaMed's Code
5 recognizes that there are many appropriate types of
6 interactions between manufacturers and providers,
7 including collaborations to advance medical
8 technologies, education and training on the use of
9 these technologies, and support for medical research
10 and education. Unfortunately, many of the
11 perceptions of inappropriate gifts linger from a
12 time prior to this Code's adoption.

13 It is essential that device companies
14 train health care practitioners on use of new
15 technologies. This supports patient access to the
16 best available technology. Accordingly, under
17 AdvaMed's Code of Ethics, activities designed to
18 educate and train health care professionals on the
19 safe and effective use of products should be
20 conducted in clinical, educational, or conference
21 settings and be held at training facilities, medical
22 institutions, or other appropriate facilities when
23 hands-on training is required.

24 Hospitality may be provided only in
25 the form of modest meals and receptions in

0081

1 connection with these programs. Manufacturers may
2 pay for reasonable travel and modest lodging costs.
3 Under AdvaMed's Code, it is inappropriate for
4 manufacturers to pay costs of meals, travel, or
5 other expenses for guests of these providers.

6 It is appropriate for manufacturers
7 to support educational, scientific, or policymaking
8 conferences through grants, modest meals and
9 hospitality, faculty expenses, and advertisements

10 and demonstrations. Such grants should be provided
11 directly to the conference sponsor or training
12 institution. Likewise, support for meals and
13 hospitality should be made directly to the
14 conference sponsor.

15 The AdvaMed Code recognizes that it
16 is appropriate for manufacturers to meet with health
17 care providers to discuss product features, contract
18 negotiations, and sales terms. Some contract
19 negotiations, such as for large capital equipment,
20 may even require negotiations over an extended
21 period of time. The Code allows occasional
22 hospitality in the form of modest meals and
23 receptions for these attendees.

24 Many health care professionals
25 provide bona fide consulting services to members,

0082

1 including research, participation on advisory
2 boards, presentations at training sessions, and
3 product collaboration. Indeed, the valuable advice
4 and professional feedback and services from
5 physicians pursuant to consulting agreements fuel
6 ongoing device development, ushering in new
7 innovations to meet patients' needs. That is why
8 consulting arrangements should be allowed and should
9 meet the following criteria:

10 Arrangements should be in writing and
11 specify services to be provided.

12 Compensation should be consistent
13 with fair market value.

14 Agreements should be entered into
15 only where a legitimate need for the service is
16 identified in advance.

17 Selection of consultants should be on
18 the basis of the qualifications and expertise to
19 address the need and should not be based on the
20 value or volume of business generated.

21 The key point is not to eliminate the
22 relationship between health care professionals and
23 the industry, but rather to ensure that it is
24 conducted properly.

25 Addressing gifts. Under AdvaMed's

0083

1 Code of Ethics, with a few exceptions, gifts to
2 providers are not allowed. The exceptions are:

3 Modest gifts that benefit patients or
4 serve a genuine medical function.

5 Other than gifts of anatomical models
6 for educational purposes or medical textbooks, any
7 gift should have a fair market value of less than
8 \$100.00. The limitation is recognized by other
9 lifescience industry codes, including the National
10 Electrical Manufacturers Association and PhRMA, the
11 representative who spoke earlier, as an appropriate
12 standard.

13 Branded promotional items of minimal
14 value related to the health care professional's work

15 or for the benefit of patients are allowed.

16 As the highlights of our Code
17 indicate, it would be inappropriate to label all
18 items of value from manufacturers to providers as
19 unacceptable gifts. In addition, device industry
20 interactions with physicians and other health care
21 providers include other arrangements that benefit
22 patient care, and access to the best medical
23 technology, that similarly should not be
24 discouraged. Among these are:

25 Product samples for the benefit of
0084

1 patients. In addition to samples for direct patient
2 use, device industry sampling may involve the use of
3 demonstration units and models for physician
4 evaluation.

5 Technical support or reimbursement
6 information. The complexity and very rapid changes
7 in medical technology require manufacturers to
8 include technical support, such as economic or
9 reimbursement information to providers.

10 We are pleased that while the Code
11 has been effective for only a few years, independent
12 survey data released earlier this year by
13 PriceWaterhouse Coopers indicates that most device
14 companies have adopted the Code. AdvaMed has
15 initiated a unique program where device companies
16 can license a unique symbol indicating an executive
17 and organizational commitment to compliance to the
18 Code if the company's CEO attests to defined
19 compliance standards and internal structures and
20 procedures to advance medical ethical interactions.

21 Let me conclude. While a
22 physician-manufacturer interaction essential to
23 device innovation and patient access to advanced
24 lifesaving technologies, the answer is not to
25 prohibit financial aspects of the relationship, but
0085

1 to manage them to ensure that they are appropriate.
2 Moreover, regulation of these arrangements not
3 tailored to the unique device industry interactions
4 could discourage valuable and beneficial
5 relationships, such as the ones we have described in
6 this testimony. AdvaMed's Code of Ethics offers a
7 well-tailored tool to guide that management of
8 device industry relationships with health care
9 professionals.

10 It is important that whatever
11 recommendations the Committee develops are
12 consistent with other State and Federal requirements
13 in this area. We urge the Committee to not take
14 actions that would harm the vital collaborative
15 process. My testimony, I won't go into that, also
16 addresses some actions in other states.

17 Finally, we would be glad to continue
18 to work with the Committee as it considers this
19 issue.

20 As the Committee realizes I am a
21 pinch hitter for the previously announced speaker,
22 Mr. Tremble, I will be very happy to note the
23 questions of the Committee and relay them to AdvaMed
24 for very prompt answering.

25 Thank you very much for the

0086

1 opportunity to appear on behalf of the Advanced
2 Medical Technology Association and to also represent
3 the Health Care Institute of New Jersey, my
4 organization.

5 MR. KNOWLTON: Just a quick question,
6 Bill, and I recognize, as you indicate, you're pinch
7 hitting, so you can certainly get back to us if you
8 don't know the answer.

9 The standard that you described in
10 the Code of Ethics you describe as voluntary
11 standards. Is that correct?

12 MR. HEALEY: Yes.

13 MR. KNOWLTON: And do you know what
14 the penetration is, what the utilization -- what
15 the level of adoption is?

16 MR. HEALEY: David, I do not know
17 that for a fact, so rather than try to hazard a
18 guess, that is something that I will have AdvaMed
19 answer for you, and they can probably answer that
20 instantaneously.

21 MR. KNOWLTON: My colleague Dean says
22 it's in the material that's been handed out to us.

23 MR. HEALEY: Okay. Dr. Blanks,
24 members of the Committee, thank you again.

25 DR. BLANKS: Okay. We'd like to next

0087

1 invite Dr. Ron White, and he'll be followed by
2 Carolyn Beauchamp.

3 MR. WHITE: Good morning. My name is
4 Ron White, and I'm a practicing surgeon in Bergen
5 County. And I really have enjoyed the other
6 speakers and the professional quality of their
7 speeches, but I'm a practicing physician. I mean,
8 if there are new regulations that are put into place
9 here, I'm the guy they're going to affect. And I
10 know you have other speakers on the agenda, but I
11 wanted to emphasize, as you listen to what I say,
12 I'm also President of New Jersey Physicians, which
13 is a new health care advocacy organization here in
14 New Jersey. Thank you for the opportunity to speak
15 before the Committee.

16 While New Jersey Physicians deeply
17 appreciates the desire of this Committee to act in
18 the best interest of the public, we are dismayed
19 that this hearing was called to challenge the
20 integrity of physicians in their dealings with the
21 pharmaceutical industry. The health and welfare of
22 New Jersey's residents always comes first in the
23 mind of New Jersey's physicians. To suggest that
24 doctors would put their patients' health at risk or

25 prescribe a less-effective drug in return for a free
0088

1 meal or a token gift is insulting and degrading.
2 Why would any responsible body even entertain this
3 possibility? What has our profession, dedicated to
4 the care and treatment of our patients, done to
5 deserve such inquiry?

6 Our members on a daily basis provide
7 charity care to patients without charge. We serve
8 our patients twenty-four hours a day, seven days a
9 week, three hundred sixty-five days a year. We
10 regularly obtain continuing education to maintain
11 currency so that we can provide optimal care to our
12 patients. And we routinely rely upon the
13 pharmaceutical companies for their products,
14 expertise and generosity to enable us to best serve
15 our patients.

16 There is a need for physicians and
17 pharmaceutical companies to work together to assure
18 that the best drugs in the correct doses for the
19 appropriate time are prescribed for patients. It is
20 critical for physicians to have the best available
21 information on the pharmacology of each drug he or
22 she may prescribe. It is important that physicians
23 be made aware of the availability of new drugs and
24 the advantages of the newer drugs over the older
25 drugs. Interactions with pharmaceutical sales

0089
1 representatives offer the best opportunity for
2 physicians to ask about the risk of new drugs and to
3 ascertain the financial cost to the patient.

4 Samples, which are often provided at
5 these meetings, are an important source of
6 medications for those patients who wouldn't
7 otherwise be able to afford their medications or who
8 need them urgently. Most often these are the most
9 vulnerable citizens of our state, the elderly, the
10 children, and the uninsured. The representatives
11 often serve as a gateway to patient assistant
12 programs provided by many of the pharmaceutical
13 companies to help patients pay for medications.

14 Just like physicians, pharmaceutical
15 companies are an essential partner in health care.
16 Together physicians and PhRMA have revolutionized
17 health care, increased longevity, and reduced pain
18 and suffering. This extraordinary partnership must
19 continue to flourish for health care to continue to
20 improve. Efforts to sever the relationship between
21 PhRMA and physicians, efforts to interfere with the
22 free flow of information between PhRMA and
23 physicians, or efforts to reduce the ability of
24 PhRMA and physicians to provide free medication for
25 patients in need will diminish, if not destroy, the

0090
1 successful partnership. Such efforts are
2 respectfully misplaced.

3 While isolated abuses have occurred

4 in the past, an extensive set of constraints now
5 governs interactions between physicians and
6 pharmaceutical companies. The American Medical
7 Association adopted its guidelines on gifts to
8 physicians from industry and incorporated it into
9 its Code of Ethics. The Pharmaceutical Research and
10 Manufacturers of America adopted a code of behavior
11 effective July 1st, 2002, governing the
12 relationships between physicians and the
13 pharmaceutical industry. The guidelines and code
14 have resulted in tremendous changes eliminating
15 behavior deemed abusive. Current claims and cited
16 articles in support of additional regulation relate
17 primarily to behavior which predated the adoption of
18 this Code.

19 The FDA has also adopted strict
20 regulations on the relationship between physicians
21 and the pharmaceutical companies. Moreover, this
22 State and the Federal Government have strong
23 anti-kickback laws which impose serious criminal and
24 civil penalties. These regulations have proven
25 effective in protecting the citizens of New Jersey

0091

1 from those very, very few physicians who place their
2 interests ahead of their patients. The actions of
3 those few should not and cannot form the predicate
4 for restrictions which will have serious negative
5 effects upon our patients.

6 We all recognize that no law or
7 regulation will stop all abuse any more than it will
8 eliminate all crime. However, current laws have
9 largely eliminated abusive behavior. In the rare
10 instance where an unscrupulous physician breaches
11 society's trust, existing law is more than adequate
12 to impose severe penalties. There is absolutely no
13 need to deny physicians vital information and to
14 deny patients samples essential for their health to
15 address theoretical future abuses which are already
16 addressed through existing law.

17 Further restrictions on relationships
18 between pharmaceutical companies and physicians will
19 do far more harm than good. Any new law or
20 regulation must be subject to the same risk benefit
21 analysis that we, as physicians, apply daily in our
22 treatment of patients. Here there's little, if any,
23 benefit to be gained from additional regulation.
24 However, there is great risk that additional
25 regulation will result in patients receiving

0092

1 suboptimal care, and patients in greatest need of
2 pharmaceuticals unable to readily obtain them, and
3 most importantly, in a breakdown of the relationship
4 between physicians and the pharmaceutical industry,
5 a relationship which has improved the lives of
6 literally billions of people throughout the world.

7 Only four states have implemented
8 such regulations. It is impossible to find any

9 evidence that these rules have had any positive
10 impact on the health of the citizens of those
11 states. There is no evidence that health care is
12 better, more accessible, or more affordable. Yes,
13 there is evidence that there are fewer visits from
14 pharmaceutical company reps to physicians' offices,
15 but so what? Less visits means less exchange of
16 information, less opportunity to compare competing
17 drugs, less ability to provide patients in need with
18 drugs they require. This evidence far from compels
19 a finding that additional regulation is desirable.

20 New Jersey has long enjoyed a
21 mutually beneficial relationship with the
22 pharmaceutical industry. New Jersey remains the
23 center of the world's pharmaceutical industry. In
24 part, because of this relationship, New Jersey is
25 able to offer state-of-the-art medical care to its

0093

1 citizens. This relationship should be celebrated,
2 not vilified. Our level of care is second to none.
3 It would be counterproductive to impose a new set of
4 burdensome regulations on New Jersey's physicians
5 when there is no hard evidence that a problem even
6 exists. Rather than correcting a problem, new
7 regulations will only reduce a physician's ability
8 to obtain the best information available to
9 facilitate patient care.

10 Furthermore, in a state in which
11 physicians already find it very difficult to
12 practice due to overregulation, any additional
13 burden will only further the perception that
14 New Jersey is an unfriendly state in which to
15 practice, causing new physicians to elect to
16 practice elsewhere and present physicians to move or
17 retire early.

18 While some may argue that public
19 disclosure is always in the public interest, the
20 reality is that a little bit of information can be a
21 dangerous thing. Requiring physicians to post the
22 value of goods, services or money they receive from
23 pharmaceutical companies only foments suspicions
24 that physicians are prescribing for improper
25 reasons. This will no doubt lessen trust between

0094

1 physician and patient and, worse, reduce patient
2 compliance. To require full disclosure will place
3 absurd burdens upon physicians. Having to account
4 for every free sample, ham sandwich, or CME credit
5 will surely result in many physicians simply
6 deciding to avoid all contact with pharmaceutical
7 representatives rather than subjecting themselves to
8 the cost and burdens associated with disclosure. As
9 such, disclosure may well have the same unintended
10 consequences as prohibition, reducing the quality of
11 health care, lowering patient compliance, and
12 limiting the free flow of essential information
13 between PhRMA and physician.

14 This hearing, quite frankly, is
15 investigating a nearly nonexistent problem.
16 Resources dedicated to eliminating this perceived
17 problem would be much better spent providing access
18 to health care for the uninsured in New Jersey,
19 particularly the children.

20 In summary, the law of unintended
21 consequences will undoubtedly result in far more
22 risk than benefit should additional regulation be
23 implemented. There is little need for additional
24 regulation in this area. There is compelling reason
25 to avoid additional regulation. Let us move on to

0095

1 the more pressing needs of New Jersey's residents,
2 quality, affordable and accessible health care.

3 Thank you for your attention.

4 MR. DE MARZO: Where do I begin?

5 No. Just to address your first point, which seemed
6 to touch on the legitimacy of this body. This is a
7 legitimate topic for inquiry, and unlike some other
8 states that went ahead and just legislated, just
9 regulated, just mandated, this is a state that chose
10 to study the problem to see if there was a problem.
11 That's what I said at the beginning of the hearing.
12 We're not here to vilify anybody. We're not here to
13 say that there is a problem. We're here to learn if
14 there is a problem and what we can do about it if
15 there is. And we're here for consumers. We're
16 here, that's our mandate, health, safety, and
17 welfare of consumers.

18 And rather than look at it as an
19 insult, I think you should look at it as how
20 important doctors are to consumers in New Jersey.
21 We regulate forty-three -- eighty professions here,
22 forty-three different boards. And you're right, we
23 would not be having a hearing such as this on
24 electricians or plumbers or some of the other
25 professions we regulate, but your decisions that you

0096

1 make on medical devices and on pharmaceuticals
2 affect life, death, health, safety, welfare of
3 patients.

4 So to imply, and I don't know if that
5 was what you meant to imply, that this is an
6 illegitimate topic, this isn't a legitimate topic
7 for the Division of Consumer Affairs to consider, I
8 would just respectfully disagree with that and say
9 not only is it a topic that we should be addressing,
10 but I think we're addressing it in the right way,
11 we're addressing it with an open mind, and we didn't
12 come in with any preconceived notions or
13 conclusions.

14 MR. WHITE: I would --

15 MR. DE MARZO: It's not a question,
16 but I felt it a statement that should have been
17 made.

18 MR. WHITE: If I could just comment.

19 Obviously we respect the integrity of this Board or
20 we wouldn't be here presenting. I think it was
21 important to get our point across that it is
22 extremely difficult to practice medicine in
23 New Jersey, much more difficult than in many other
24 states for a variety of reasons, and this
25 potentially can add one more burden to an area where

0097

1 we just don't perceive that the problem exists.
2 Existing regulations are sufficient to take care of
3 the problem, we believe.

4 DR. CHEEMA: Just one --

5 MR. KNOWLTON: I'd like to add to
6 that, too. Doctor, I take your point. But I think
7 it's an appropriate level of inquiry for this
8 group. I think, as you appropriately know, and as
9 Larry noted, the Board is not prejudging, but the
10 fact that they are creating an inquiry into the
11 issue.

12 You acknowledged in your testimony
13 that there are current laws in place that stop
14 abuses by a small group of physicians. Well, how
15 small is that group and what is the nature of that
16 and does it require additional steps is exactly what
17 this body is being asked to deliberate over, and
18 they're doing it in the public eye and they're doing
19 it in the public way. They're not -- this isn't
20 something that you get in a mailer when the Board of
21 Medical Examiners gives a new rule. This is a
22 public debate.

23 So I take your point that you -- the
24 position of you and your organization is that this
25 problem doesn't exist to a level that these -- this

0098

1 level of regulation, and that's pertinent and
2 appropriate testimony, and I think that's something
3 that this Board is going to consider.

4 I don't know anybody -- since I've
5 been sitting on this Commission, I don't know
6 anybody that's prejudged this issue. They're trying
7 to find the facts, and this is an important piece of
8 that. But I prefer -- I run an institute that
9 fights high for disclosure, and I prefer for this
10 debate to take place in public. So I really applaud
11 the fact that this has at least the kind of public
12 hearing to it.

13 DR. CHEEMA: A question. In your
14 written statement, you mentioned the best way to
15 learn about the drugs and medication is from the
16 pharmaceutical rep. I'm a practitioner just like
17 you in the same boat. I don't think that we should
18 learn -- the best person to teach us is a
19 pharmaceutical rep who does not have any background
20 in medical education and we totally rely on him,
21 what he or she tells us.

22 MR. WHITE: Doctor Cheema, I don't
23 think I said that exactly. I think the

24 pharmaceutical reps are an excellent way to find out
25 about new medications, to find out a lot about those
0099

1 medications. They certainly should not be the sole
2 way that we find out. And I speak for myself and
3 most physicians in that we all read professional
4 journals, we go to professional conferences, we talk
5 to our colleagues. There's a variety of ways that
6 we find out about new medications and new medical
7 devices, and certainly we wouldn't rely on industry
8 to be the sole source of that. But I think they're
9 an important contributing source of that type of
10 information.

11 DR. CHEEMA: I'm glad you clarified.

12 MR. WHITE: Thank you.

13 DR. BLANKS: A little bit out of
14 order. Carolyn Beauchamp, please.

15 MS. BEAUCHAMP: Good afternoon. I'm
16 Carolyn Beauchamp. I'm the President of the Mental
17 Health Association of New Jersey. And I'm learning
18 a great deal. I'm pleased to be here today.

19 I'd like to give you a different
20 perspective of pharmaceutical companies and mental
21 health. That's something that you haven't heard yet
22 this morning. We are a statewide nonprofit private
23 advocacy organization. Our mission is to, it's a
24 little grandiose, cure mental illness, promote
25 mental wellness, both for children and adults in the
0100

1 State of New Jersey, and we do that through
2 advocacy, through education, through training, and
3 through work in the community.

4 So I just want to be clear that we do
5 not do any clinical services. We do not work
6 directly with doctors or medications. We do not
7 work with therapists. And we do not refer
8 specifically to them. So our relationship with our
9 pharmaceutical companies tends to be quite
10 different. And when I say this is interesting, I'm
11 hearing issues that I hadn't thought about very
12 specifically. So this is an educational experience
13 for me.

14 Our relationship with pharmaceutical
15 companies as you would know probably right away has
16 to do with the fact that many of the people, the
17 consumers that we work with, are taking some very
18 powerful psychotropic and antidepressant drugs,
19 which over the years, I would say since the 1960s,
20 have been probably the most important piece of their
21 ability to leave institutions and to live in
22 communities.

23 We have watched pharmaceutical
24 companies do the research. We have watched them
25 come out with products. We have watched consumers
0101

1 become productive members of society. And part of
2 our job is to work with consumers, speak with them,

3 speak for them in an effort for them to rejoin
4 society, and that is certainly helping and that's
5 happening.

6 The pharmaceutical companies work
7 with us in advocacy efforts, and one of the biggest
8 ways we do that is around the State budget. The
9 Medicaid budget is extremely important, because the
10 majority of our folks tend to be poor, they tend to
11 be on Medicaid or Medicare Part II, which is a
12 nightmare, it's very confusing, but we struggle with
13 it. And by working with Pharmaceutical Partners, we
14 have been able, all of us together, so far to defeat
15 efforts to cut Medicaid, to add copays, to have a
16 preferred drug list, and as you would know
17 immediately, that is a partnership that has been
18 extremely productive for our consumers.

19 In addition, our advocacy and our
20 community education initiatives have been supported
21 financially by a number of corporations and a number
22 of pharmaceutical companies over the years. And I
23 would say perhaps 2 percent of our budget is
24 attributable to pharmaceutical companies. What they
25 help us with is developing programs such as voter

0102

1 registration campaigns, campaigns to work with
2 consumers to become advocates, to visit legislators,
3 to begin to speak for themselves and to take an
4 active role in politics and in their own recovery.
5 We have been very successful at that, and that's
6 perhaps one of the key points that we're known for
7 in the state.

8 Our relationship has been established
9 from the beginning with very clear structure and
10 clear guidelines. We work -- our success is based
11 on the fact that we are neutral politically, that we
12 do not come out in favor of any particular entity
13 unless it is beneficial to our consumers. So the
14 structure that we establish with pharmaceutical
15 companies from the very beginning and which they
16 reciprocate with us and always have is that we set
17 the guidelines. If they are funding a program, it
18 is our program. We do not tout or promote any
19 particular drug or any pharmaceutical company. We
20 work collaboratively. The agenda is always ours,
21 and we do work together on advocacy issues when it
22 seems as though it's going to benefit consumers.
23 We've met with nothing but respect and reciprocity
24 in a very positive way with our pharmaceutical
25 colleagues, and I suspect that that will continue.

0103

1 Now, I can say that because we have
2 no drugs that are connected and it isn't
3 specifically to the point that you're looking for
4 input on. But I feel as though as I look at it
5 systemically and I'm listening this morning and part
6 of the afternoon to what people are saying, it feels
7 to me as though this is a real systems issue. And

8 someone just said we depend on pharmaceutical
9 companies. And yes, we do. And part of the reason
10 we depend on them is because they do research that
11 other entities are not doing. And particularly
12 around psychiatric meds, they are the reason --
13 they are one of the primary reasons that we've got
14 people out of institutions.

15 I used to work at Greystone Hospital
16 years ago in the '70s, and we had 3,000 patients
17 there. We now have 500. And they just opened a new
18 facility. The only reason we've been able to close
19 one psychiatric hospital and downsize others is
20 because of the drugs that people are taking.

21 Am I thrilled with the drugs? Not
22 necessarily, because there's a combination of side
23 effects, of weight gain, of other illnesses that we
24 have to deal with, and we want the pharmaceutical
25 companies to deal with it as well. We want them to

0104

1 have more time as they look at drugs and start
2 dealing with the health issues.

3 The other systems piece that I keep
4 thinking about as I'm sitting here is that there's a
5 core issue here, that doctors are not getting and
6 don't have time to get the training that they
7 desperately need. If you talk to -- psychiatrists
8 are the ones that we're the most familiar with.
9 They are crunched by managed care, by the
10 accountability, by the insurance companies, and they
11 are desperately trying to see patient after
12 patient. How convenient for them that
13 pharmaceutical reps are coming through the door and
14 bringing them information. That's a very good
15 position to be in if you are interested in moving
16 your products.

17 I don't necessarily blame -- I don't
18 blame the pharmaceutical companies for that. I'm
19 concerned that we need other ways to get information
20 to our doctors. There has to be a better way. They
21 don't get what they need. They're not getting the
22 education they need. And particularly our primary
23 care docs don't know enough about psychiatric
24 illness. They don't know enough about how to
25 medicate. We frequently find that our patients are

0105

1 undermedicated. And we struggle with how can we get
2 to our docs, how can we get more information.

3 So I understand the concerns and I
4 understand there's probably reason for some concern,
5 but I think it's more of a systemic issue.

6 Thank you. And are there any
7 questions I can answer?

8 MR. DE MARZO: Thanks, Carolyn.

9 MS. BEAUCHAMP: Thank you.

10 DR. BLANKS: We're back on schedule

11 now. Theresa Barrett and Stephen Nurkiewicz.

12 Forgive me if I'm -- did you want to speak

13 together? Okay.

14 DR. NURKIEWICZ: Good afternoon. I
15 represent -- my name is Steve Nurkiewicz and I'm a
16 family doc, and I represent the New Jersey Academy
17 of Family Physicians as their Vice President. I'm
18 eighteen years in family practice in Hammonton,
19 which in case you weren't sure is the blueberry
20 capital of the world. So I've been in the trenches
21 for a while, and I'd like to give you a current view
22 of prescribing habits.

23 The real control and influence over
24 the last two years I think is a combination of
25 Walmart, pharmacy benefit managers, and the

0106

1 insurance companies. For example, one of my
2 patients this week fell into the doughnut hole and
3 said to me, I'm going to stop my medications unless
4 you can find me the \$4.00 equivalent at Walmart. We
5 had to revamp his entire program, which fortunately
6 was only three major illnesses, and we were able to
7 come up with an affordable plan. The option was
8 that or nothing.

9 The PBMs like Caremark fax me about
10 ten to fifteen times a day explaining that there's a
11 tier system and a preferred drug system. So even if
12 I enjoyed my salad from Pfizer that day, if their
13 drug is not on the Caremark formulary, there's no
14 way to get that easily. For example, Protonix and
15 Nexium and the PPIs, one insurance company would say
16 Protonix is the preferred. I won't know that ahead
17 of time. I hope for the best. I pick the best
18 medicine for the patient. The pharmacy will call me
19 back and say no, you missed. I might have to switch
20 to Nexium. So it's the PBMs and PhRMA that sort of
21 negotiate some of that outside of my office.

22 Thirdly is the insurance companies
23 when they insist on a preauthorization. I'm sure
24 the physicians are well aware of that situation.
25 This week I had a patient who was unable to get

0107

1 Cymbalta without failing thirty days of another
2 medication mandated by the insurance company the
3 patient selected.

4 So I just wanted to conclude by
5 saying that in the last two weeks, these are some of
6 the things PhRMA brought to my office, some safety
7 issues regarding Singulair and some post-marketing
8 information about suicide. I thought that was very
9 relevant. There's black box warnings that come up
10 very quickly, like the Actose and the Avandia
11 issues. Although I did get that in the press as
12 well, there are some other ways that PhRMA helps my
13 office. If there's a recall or a discontinuation
14 two weeks ago or three weeks ago, Exubera was
15 discontinued for further production, not that there
16 was a safety issue, it was a financial issue, I
17 believe, Pfizer had just pulled the drug, but they

18 were at least able to give us some information about
19 how to convert patients back to insulin.

20 If there's new indications, for
21 example, for fibromyalgia and the dosing is
22 different than for seizures or for postherpetic
23 neuralgia, sometimes I know the next day and my
24 patients will also know the next day. So that's
25 crucial information.

0108

1 So I think that the pressures on the
2 physician are not quite like they were in the old
3 days. I think we have to deal with where the
4 consumers are getting their medication and how much
5 they're paying, like the \$4.00 plans at Walmart. I
6 have to carry that in my pocket so that my patients
7 who have no insurance at least can afford something
8 and get some kind of treatment for their medical
9 illnesses. And of course the insurance company
10 world and the PBM world, I never get a salad from
11 Caremark.

12 So I'd be happy to answer any other
13 questions.

14 MS. JOYCE: The communications that
15 you have with the representatives that bring this
16 obviously important information, how is that
17 transmitted? Through a visit? Through E-mail?
18 How -- what's the manner by which that
19 communication takes place.

20 DR. NURKIEWICZ: I can speak for my
21 office. I have pharmacy representatives come into
22 the front and they have to sign in, and only one at
23 a time is allowed back to the sample closet to put
24 their samples in. At that point in time, I will
25 stop, they need a signature for samples, and then at

0109

1 that point they would either give me a reprint --
2 for example, on Friday there was a JAMA article that
3 was given to me which was reprinted. That's the
4 peer review journal. It wasn't PhRMA literature
5 that usually unfortunately winds up in the trash,
6 but the real good stuff is given to me as well, and
7 I keep that. And then they're pretty much escorted
8 out. And if there's another one waiting, they can
9 come back.

10 DR. BLANKS: Do you have any opinion
11 about CME and industry support for CME?

12 DR. NURKIEWICZ: Yes. Theresa is
13 going to go into detail on that.

14 DR. BLANKS: Oh.

15 DR. NURKIEWICZ: Thank you.

16 MS. BARRETT: Hello. My name is
17 Theresa Barrett I'm the Deputy Executive
18 Vice President for the New Jersey Academy of Family
19 Physicians. And one of our main missions is to
20 provide education for family physicians in the State
21 of New Jersey. So I'd like to talk to you a little
22 bit about the procedures for CME education and

23 pharmaceutical support.

24 Physicians are dedicated to lifelong
25 learning. Once they have graduated from their

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1 residency programs, the way they pursue this
2 lifelong learning is through continuing medical
3 education. Those of us who are involved with the
4 design and the delivery of physician education are
5 committed to providing nonbiased, evidence-based
6 educational programs which we hope will ultimately
7 lead to better patient care.

8 The Accrediting Council for
9 Continuing Medical Education, or ACCME as it is most
10 commonly called, is one of the overseeing bodies for
11 continuing medical education, or CME, in the United
12 States. The American Academy of Family Physicians
13 and the American Osteopathic Association also
14 oversee CME specific to their members. The ACCME
15 sets the standards for the accreditation of all
16 providers of CME activities, as well as ensures the
17 quality for continuing medical education that
18 physicians receive.

19 As you are probably well aware, most
20 of the CME that is offered in the United States is
21 sponsored by commercial interests. What you may not
22 be aware of is the level of regulation that is in
23 place to ensure that CME programs are nonbiased and
24 free of commercial influence. The ACCME defines a
25 commercial interest as "any entity producing,

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1 marketing, reselling, or distributing health care
2 goods or services consumed by, or used on,
3 patients."

4 In order to ensure that CME programs
5 are free of commercial bias, the ACCME has issued
6 "Standards for Commercial Support." These
7 standards are designed to ensure the independence of
8 CME activities. There are six Standards that
9 encompass the following areas.

10 Standard 1 is Independence. A CME
11 provider must ensure that all aspects of the CME
12 activity were made free of the control of the
13 pharmaceutical interest.

14 Standard 2 is Resolution of Personal
15 Conflicts of Interest. The provider must be able to
16 show that everyone who is in a position to control
17 the content of an educational activity has disclosed
18 all relevant information, financial relationships
19 with any commercial interest to the provider and
20 mandates that an individual who refuses to disclose
21 information will be disqualified from being involved
22 in the activity in any capacity. The provider must
23 also have a policy in place to identify and resolve
24 all conflicts of interest prior to the educational
25 activity being delivered to the learners.

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1 Standard 3, Appropriate Use of

2 Commercial Support. The provider makes all
3 decisions regarding disbursement of funds for the
4 educational activity and there are strict procedures
5 in place to ensure appropriate disclosure and use of
6 funds.

7 Standard 4, Appropriate Management of
8 Associated Commercial Promotion. Arrangements for
9 commercial exhibits or advertisements cannot
10 influence planning or interfere with the
11 presentation of the activity. Product-promotion
12 material and all product-specific advertisement of
13 any type is prohibited in or during the CME
14 activities.

15 Standard 5, Content and Format
16 Without Commercial Bias. The content of a CME
17 activity must promote improvements or quality in
18 health care and not proprietary business interest of
19 a commercial interest. Also, presentations must
20 give a balanced view of all therapeutic options.

21 Standard 6, Disclosures of
22 Relevant -- Disclosures Relevant to Potential
23 Commercial Bias. Individuals must disclose to
24 learners any relevant financial relationships,
25 including the name of the commercial interest and

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1 the nature of the relationship the person has with
2 each commercial interest. If no financial
3 relationship exists, the learner must be informed of
4 this as well. Also, the source of all support from
5 the commercial interest must be disclosed to the
6 learners, and all of this must occur before the
7 beginning of the educational activity.

8 The New Jersey Academy of Family
9 Physicians is a developer of CME programs in
10 New Jersey. Sometimes we are able to develop
11 educational offerings as a result of an educational
12 grant from a commercial interest. However, we also
13 receive funding for CME programs from the State of
14 New Jersey, specifically the Department of Health
15 and Senior Services, and through private foundations
16 or agencies, such as the American Cancer Society.
17 We also receive support from industries such as
18 insurance companies, medical malpractice companies,
19 and electronic medical records companies, all
20 companies which would not be considered commercial
21 influences or commercial interests. Regardless of
22 where the funding comes from, the NJAFP has a
23 process in place for the development of educational
24 programs that ensure that the content of the program
25 is free from bias and undue influence, and we always

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1 clearly disclose the source of any funding we
2 receive.

3 In developing CME programs, we
4 strictly adhere to the ACCME Standards for
5 Commercial Support, as I outlined above. We begin
6 the CME process with a needs assessment where we

7 look for knowledge gaps between what the physician
8 currently knows and what they should know. Once the
9 need has been identified and the learning objectives
10 have been developed, we convene a panel of experts
11 to design the content of the program. We seek
12 members who are experts in their specialties, and
13 they must disclose all financial interests before
14 they are allowed to participate in the panel.

15 NJAFP follows an evidence-based
16 process. Evidence-based medicine is the integration
17 of individual clinical expertise with a
18 conscientious, explicit, and judicious use of
19 current best evidence in making decisions about the
20 care of individual patients. We ensure that all of
21 our educational programs are anchored in the most
22 current medical evidence available.

23 Once the program is designed, it goes
24 through several layers of review before it can be
25 accredited for CME. It goes back to the faculty for

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1 a final review, it goes through a compliance officer
2 at the NJAFP, and it goes through the CME division
3 of the American Academy of Family Physicians before
4 it is offered to the Family Physician audience.

5 As providers of CME, the NJAFP
6 understands and actively works to ensure that
7 educational programs sponsored by the Academy are
8 held to the highest standards of ethics and
9 quality. Our dedication to delivering the best
10 education, free of bias and based in current medical
11 evidence, ensures that we are serving the best
12 interests of our members and their patients.

13 Thank you. Any questions?

14 DR. BLANKS: Ms. Barrett, do you know
15 that there's a difference between category one and
16 category two CME? I'm just wondering, when
17 physicians attend dinner meetings, promotional
18 dinner meetings, is that considered an educational
19 experience, albeit not ACCME accredited or category
20 one? Doctor?

21 DR. NURKIEWICZ: I can answer that.
22 There's a line in the sand. If you're a CME, you've
23 been accredited, reviewed, you get credits towards
24 your professional CME certification. If you go --
25 happen to go to a dinner meeting that's sponsored by

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1 a pharmaceutical company, there's no credit, you
2 don't get credit for that or anything. Is that your
3 question?

4 DR. BLANKS: No not exactly. And
5 there are some dinner meetings that are part of
6 ACCME approved CME. I'm talking about informal
7 medical education. Would you -- either of you or
8 your members, would you consider an educational
9 presentation or a presentation given at a
10 promotional meeting to be medical education,
11 although informal, not officially accredited.

12 DR. NURKIEWICZ: Well, I have
13 attended those type of diner meetings. And the
14 primary slide deck is usually going over at least
15 recently a current peer-reviewed research,
16 randomized trial, and that they emphasize that, I'm
17 sure, you know, for their medications they want to
18 present. But typically that's what I see. It will
19 be an educational experience with some bias that we
20 know ahead of time.

21 MS. BARRETT: I want to make sure I
22 understand your question. Are you asking if a
23 physician attends a presentation that has a meal
24 associated with it?

25 DR. BLANKS: No.

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1 MS. BARRETT: No? Could you restate
2 your question for me?

3 DR. BLANKS: Well, it was --

4 MS. JOYCE: What do you consider to
5 be the value, the educational value of the talk that
6 may be associated with that kind of informal
7 exchange, the promotional dinner or something of
8 that, what would you consider to be the educational
9 value of that?

10 MS. BARRETT: A promotional dinner
11 will never be accredited for CME. So the physicians
12 up front know that they're not getting CME, and they
13 know up front that they are attending a promotional
14 event. I think it is up to each individual attendee
15 at that meeting to determine whether or not they are
16 getting any educational value. I always think that
17 there is some value to learning what's out there in
18 the market, what drugs are being prescribed,
19 certainly what drugs patients are seeing advertised
20 on television. And there has to be an element of
21 critical thinking involved so that the people that
22 are attending can compare what they've just heard to
23 something else they already know. A physician has
24 to think critically about the information they are
25 receiving, otherwise...

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1 MS. JOYCE: Thank you.

2 DR. NURKIEWICZ: Just a brief
3 follow-up on that. The last -- one of the last
4 ones I went to was Januvia. That's rather new, a
5 whole new science behind it. So I went to one of
6 the dinner meetings there simply to gather the
7 package inserts, the literature, you know, talk to
8 my other colleagues and all that, knowing it was a
9 pharmaceutical-sponsored dinner, no CME involved,
10 but there was just a crucial picking up as much
11 information as I possibly can about it.

12 DR. BLANKS: So you would consider
13 that a form of --

14 DR. NURKIEWICZ: There's learning
15 going on.

16 DR. BLANKS: -- informal medical

17 education?

18 DR. NURKIEWICZ: Yes.

19 MS. BARRETT: Thank you.

20 DR. NURKIEWICZ: Thank you.

21 DR. BLANKS: Jessica Goldsmith

22 Barzilay.

23 MS. GOLDSMITH BARZILAY: Hello,
24 everybody. I'm Jessica Goldsmith Barzilay, and I'm
25 the Assistant Director of a nonprofit organization,

0119

1 The Family Resource Network, and its affiliate
2 organizations, which are the Epilepsy Foundation of
3 New Jersey, Autism Family Services of New Jersey,
4 Caregivers of New Jersey, and The Family Support
5 Center of New Jersey.

6 Our organization provides services to
7 the over 836,000 caregivers in New Jersey. That
8 number is growing every day. Those are caregivers
9 of individuals with mental health issues, with
10 chronic health issues, with developmental
11 disabilities, with issues of aging.

12 We also provide services for the over
13 100,000 individuals with autism in New Jersey, sadly
14 that number is growing at epidemic proportions, and
15 the 125,000 people in New Jersey who live with
16 epilepsy.

17 I want you to know we're not a
18 medical organization, and our staff doesn't have any
19 medical expertise, but we get a lot of questions
20 from the people we serve, a lot of medical
21 questions. A lot of the consumers we serve rely on
22 us for information, cutting edge up-to-date
23 information that they can't always access because
24 they don't always have access to specialists. We
25 especially get a lot of questions from our consumers

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1 who have epilepsy. Epilepsy is a complex medical
2 condition. There are scores of medications and
3 medical devices and surgeries that help people with
4 epilepsy. Many of those medications have a narrow
5 therapeutic index, which means they can't easily be
6 switched for generic medications. There are
7 different medications or procedures that one would
8 prescribe if you're prescribing to a woman who's in
9 childbearing age or to a senior who is taking a
10 whole host of different medications.

11 So we get a lot of those questions
12 and we really rely on our partners in the medical
13 community and the pharmaceutical industry to make
14 sure that we have that information so that we can
15 answer people's questions, and when drugs are
16 recalled, we can get to the people who are taking
17 those medications and let them know about that. And
18 that's very important to us.

19 And so I guess we really want to ask
20 this Committee -- we want to caution this Committee
21 to proceed with care, because we worry that anything

22 that would hamper the flow of information from
23 pharmaceutical companies to physicians would have
24 the unintended consequence of cutting off the
25 information to the consumers who need it so badly.

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1 I also want to let you know that we
2 get a lot of calls from people who say they've
3 received a sample medication from their doctor. A
4 lot of the people we serve take medication every
5 day. But when that sample runs out, they'll have no
6 way of paying for their medication. And that sample
7 that the doctor gives us the time we need to
8 explore other options to find ways for that
9 individual to pay for their medication, whether it's
10 through a social service program or pharmaceutical
11 assistance program. So we actually find that very
12 helpful.

13 I also want to let you know that we
14 rely directly on the generous support of the
15 pharmaceutical industry to allow us to provide
16 education for our consumers that's not even medical
17 information. Earlier this month we held our
18 National Caregivers conference, November is
19 Caregivers Awareness Month, and we had over three
20 hundred twenty people attend. That was caregivers
21 and professionals who provide support to
22 caregivers. And pharmaceutical companies help make
23 that possible through donations. Their donations
24 provided scholarships for individual caregivers to
25 come to the conference. Their donations made it

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1 possible for us to provide respite or care for
2 individuals who develop mental disabilities so the
3 parents didn't have to worry during the conference
4 and they could go and learn.

5 We have a lot of sponsors of our
6 conference. So they don't get any information about
7 a pharmaceutical company that sponsors their
8 scholarship. It also allowed us to bring in a big
9 keynote speaker that we choose that has nothing to
10 do with the medical industry. In this case we
11 brought in Geri Jewell, who's a comedian who has
12 cerebral palsy, and those contributions make it
13 possible for us to do those things.

14 I do want to say we would never want
15 to see a doctor influenced in a prescription or a
16 medical decision based on a compensation or a gift
17 that they were getting from a pharmaceutical
18 company. And we really don't think that we've seen
19 that. And it seems like there's regulations in
20 place in the pharmaceutical industry to make sure
21 that that doesn't happen. But we want to be careful
22 as you move forward with possible regulations that
23 there aren't unintended consequences and fallout for
24 folks like us who are just trying to educate our
25 consumers.

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1 And I'm going to digress a little
2 bit, but I want to sort of give an example of how
3 some recent legislation has had some of those
4 unintended consequences for nonprofit
5 organizations.

6 In New Jersey, there was recent
7 legislation, and you guys are probably more familiar
8 with it than I am, the pay-to-play legislation, and
9 it was based on a really good concept, you know, you
10 want to make sure that foundations aren't getting
11 special favors by giving contributions to
12 candidates. What's happened is instead of the
13 candidates or the contributors having to disclose
14 those contributions, we've been asked as nonprofit
15 agencies to poll all of our Board members and have
16 them disclose to us all of their political
17 contributions. And I can tell you that's been
18 really uncomfortable to do and it's put a little bit
19 of an awkward strain on our relationship with our
20 own Board, and we believe it's going to have the
21 effect of having a lot of people not want to serve
22 on those boards, because it is a private question.
23 And certainly when the legislation and regulations
24 were made, nobody intended it to have that negative
25 consequence on nonprofits. So we want that to be

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1 something that people think about.

2 We do know that in the coming
3 decades, there are going to be more medical
4 advancements that keep more seniors alive on
5 medications or more people with disabilities able to
6 live full lives using medical devices. And so we
7 expect to have a lot more consumers coming to us
8 with a lot more complex questions. We don't expect
9 to see a lot more money coming from the State to do
10 the work that we do. So we're hoping that we'll be
11 able to continue to rely on our partnerships with
12 the medical community and the pharmaceutical
13 community so we can make sure that those people who
14 are really most vulnerable and who really don't have
15 access to that information can get that
16 information.

17 I also want to say that I only
18 learned about the details of this hearing yesterday,
19 and so I don't have anything written up, and I
20 apologize for not being able to hand you something
21 that I had written up. And as I listened to the
22 speakers earlier today, I thought, wow, everybody
23 has a lot of statistics and I don't have any. And
24 I'm not sure if I had more time that I would have
25 them. But I still felt it was important.

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1 And I want to thank you for the
2 opportunity to make sure that those individuals,
3 those consumers that we serve that, again, are
4 already vulnerable and don't always have access to
5 medical specialties and specialists, that they're

6 able -- that we can make sure that they're
7 protected and that this legislation or regulations
8 doesn't affect them in any way.

9 And I thank you for the opportunity
10 to speak today.

11 DR. BLANKS: Do you have a -- do you
12 pay physicians at all through your organization?

13 MS. GOLDSMITH BARZILAY: No. We
14 wouldn't have the money to pay physicians through
15 our organization. We do have physicians who sit on
16 our professional Advisory Boards. So we go to them
17 and we say, okay, we have a -- you know, somebody
18 has a question about brain surgery, where should we
19 direct them. So we rely on them for that
20 information, or they let us know when a drug is
21 recalled. But we don't pay physicians in any way.
22 And if we have like -- if we have like a
23 neurologist referral list, it has to include all the
24 neurologists in the state and those who specialize
25 in epilepsy. We don't direct to just a few of them.

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1 DR. BLANKS: And the money that you
2 get from the industry, does that come through their
3 philanthropic foundation or is that --

4 MS. GOLDSMITH BARZILAY: It can, but
5 it usually comes -- they tend to have community
6 education. It comes from a few different places,
7 but very often it's a community education
8 department. And they'll say, okay, you can have a
9 \$5,000 unrestricted education grant, you're doing a
10 National Caregivers conference, you know, handle
11 that however you'd like. They also, you know, might
12 support a golf outing, and that will tend to come
13 through a different department, but they never get
14 access to specifically speak at something that we
15 do. They tend to get a thank you in our sponsorship
16 books for their donations.

17 Thank you.

18 DR. BLANKS: Bill Crowe?

19 MR. CROWE: Hi. My name is Bill
20 Crowe, and I am the Associate Executive Director of
21 the New Jersey Association of Mental Health
22 Agencies.

23 Our association is a statewide trade
24 association representing 125 nonprofit,
25 hospital-based and freestanding community mental

0127

1 health agencies that provide behavioral health
2 services across the entire state. In aggregate, our
3 members serve children and adults with mental
4 illness and behavioral disorders more than one
5 million times annually and provide the full spectrum
6 of services and treatment to help individuals with
7 mental illness and emotional and behavioral and
8 substance abuse disorders work towards recovery.

9 I'm here today to discuss several
10 important programs critical to the welfare of

11 consumers served by nonprofit mental health care
12 agencies.

13 Our member agencies serve as the
14 safety net for the community. Many of their clients
15 have low incomes or rely on government assistance.
16 The availability of medication samples is very
17 important in assisting those with a mental illness
18 when they are unable to obtain their prescriptions
19 immediately. For example, when a patient is
20 discharged from a state psychiatric institution,
21 sample medications can help bridge the gap until
22 paperwork and payment mechanisms are finalized.

23 In addition to free samples, the
24 pharmaceutical industry has a wide variety of
25 patient assistance programs to help low-income,

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1 uninsured patients. In New Jersey alone, over
2 200,000 patients have gained access to free or
3 nearly free medications through the Rx4 New Jersey
4 program, and nationwide, over 4.2 million patients
5 have been helped by the pharmaceutical industry's
6 partnership for prescription assistance.

7 Providing free samples and patient
8 assistance is vital for helping consumers access the
9 medications they need.

10 Additionally, the development of new
11 and improved medications to treat mental illness is
12 key to enabling individuals to live full and
13 productive lives in the community.

14 Since government does not adequately
15 support research and development, the pharmaceutical
16 industry, through its clinical research and
17 development, is counted upon to invest in the
18 development of more effective medications with fewer
19 side effects. The development of more effective
20 medications over the last few decades have been the
21 key to enabling thousands of New Jersey residents to
22 live outside institutional walls.

23 The pharmaceutical industry also
24 plays a key role in helping consumers, family
25 members and our service providers remain informed

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1 about the latest developments in the field and best
2 practices in treatment and service delivery.

3 By supporting efforts to battle
4 stigma, help family members cope with an illness of
5 a loved one, encouraging consumers to lead healthy
6 lives, and training staff on new techniques in
7 caring for consumers, the pharmaceutical industry is
8 playing a key role in improving the lives of those
9 with a mental illness.

10 The support of the industry is
11 critical to enabling organizations to bring in
12 experts to present best practices and other critical
13 information for mental health practitioners.

14 For our association and other
15 nonprofit stakeholders as you've heard, these

16 educational funds are provided by companies and
17 foundations without any contractual obligations or
18 control over content and are critical to making the
19 training affordable for nonprofits struggling with
20 limited resources.

21 It is the responsibility of the
22 giving party and the receiving party to maintain
23 controls that ensure that there is no undue
24 influence. The pharmaceutical industry has taken a
25 lead role in ensuring that their practices are

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1 transparent, while nonprofits have strict policies
2 regarding how funds are accepted. For example, in
3 our association, our presentations never focus on a
4 particular medication, but rather on treatment
5 policies and practices.

6 The benefits to these trainings are
7 clear. The nonprofit employee has the opportunity
8 to learn about practices that have been proven
9 effective elsewhere. The consumer experiences
10 improved services and improved outcomes.

11 The pharmaceutical industry and
12 society also benefit from the greater likelihood
13 that persons suffering from mental illness will
14 adhere to treatment and continue to thrive in the
15 community.

16 In a time of limited resources, as
17 the nonprofit industry struggles to meet the needs
18 of hundreds of thousands of New Jersey residents,
19 the pharmaceutical industry's support is key -- is
20 a key component to improving the mental health of
21 those we serve.

22 Thank you.

23 Any questions?

24 Thank you.

25 DR. BLANKS: Two more speakers that

0131

1 are preregistered. Thomas Grady.

2 MR. GRADY: Good afternoon. My name
3 is Tom Grady, and I serve as the Director of
4 Advocacy & Public Affairs for the Brain Injury
5 Association of New Jersey.

6 MR. KNOWLTON: Can you speak up. We
7 can't hear you.

8 MR. GRADY: Can you hear me now?

9 Good afternoon. My name is Tom
10 Grady. I serve as Director of Advocacy & Public
11 Affairs for the Brain Injury Association of
12 New Jersey. We are a statewide organization in
13 existence since 1981.

14 Our mission is to provide education,
15 outreach, prevention, advocacy and support services
16 to all persons affected by brain injury and to the
17 general public. We envision that all people in the
18 State of New Jersey will be aware of the cause and
19 the consequence of brain injury and have access to
20 appropriate services. The Brain Injury Association

21 of New Jersey will be recognized as the leading
22 New Jersey organization helping people affected by
23 brain injury. We will respect the dignity and worth
24 of all people, support individual choice, and
25 respond to issues with integrity and courage.

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1 I'm happy to say that we're in the
2 process of revising our mission and vision statement
3 because every time I read that whole vision
4 statement it takes me five minutes.

5 To fulfill our mission and vision, we
6 partner with those in both the medical and
7 pharmaceutical fields to ensure that those impacted
8 by TBI, traumatic brain injury, receive optimal care
9 and work towards maximizing their quality of life.

10 The Brain Injury Association of
11 New Jersey is a proud partner of Rx4 New Jersey,
12 which you heard several times about already today,
13 through which we have worked with the pharmaceutical
14 and medical technology industry and their
15 association, the HealthCare Institute of New Jersey,
16 to give people with brain injury the opportunity to
17 access low- or no-cost medicines. Rx4 New Jersey
18 helps people, including those with traumatic brain
19 injury, determine whether they're eligible for
20 discounted medicines provided through drug companies
21 and government-sponsored programs.

22 Brain injury is a devastating
23 injury. It affects many, if not all, aspects of a
24 person's life. Some people with brain injury become
25 financially challenged as a result of the

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1 disability. Doctors' bills, lack of employment, and
2 inability to save money are some of the negative
3 financial results of TBI. The inability to be
4 financially secure can, for some, lead to an
5 inability to pay for medicine.

6 The Association believes the industry
7 has recognized the financial hardship some
8 New Jerseyans are subject to. In response, they
9 became responsible corporate citizens by providing a
10 service that can enable some financially-challenged
11 people to receive the medicines they need to not
12 only maximize their quality of life, but to continue
13 their life.

14 Through Rx4 New Jersey, we at the
15 Brain Injury Association of New Jersey believe the
16 industry has shown it is both a responsible citizen
17 and a resource to people who need medicine. We
18 appreciate their efforts.

19 Thank you.

20 DR. BLANKS: Thank you.

21 And Bonnie Arkus.

22 MS. ARKUS: Good afternoon. I'm
23 Bonnie Arkus from the Women's Heart Foundation. And
24 thank you very much for inviting me to comment on
25 this issue.

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1 As a nonprofit organization based in
2 Trenton, New Jersey, we're dedicated to the
3 8 million women who suffer from heart disease in
4 this country and the 56,000 women in New Jersey who
5 have heart disease, as well as prevention of heart
6 disease. We're the only nonprofit organization in
7 the country, perhaps the world, that designs and
8 implements demonstration projects for preventing
9 heart disease. And we run the Trenton Teen Esteem
10 Health and Fitness Program, and this is our fourth
11 year of operation there, and we're proud to report
12 some very positive results in reversing some of the
13 risk factors for heart disease and diabetes in young
14 girls.

15 We are dedicated to designing gender
16 specific care for women in society, and in the past
17 we have conducted medical conferences to instruct
18 doctors and nurses about the specifics on womens'
19 heart care. Unfortunately we've had no
20 pharmaceutical support for the past four-and-a-half
21 years, and we have not had any medical conferences.
22 And if you do a web search, you'll find that there
23 aren't any significant medical conferences going on
24 anywhere in the country right now on medical care
25 for women and heart disease. And this is just very

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1 sad for all the women who suffer from heart disease
2 or are candidates for a heart attack.

3 We think it's very important that we
4 receive pharmaceutical assistance in this area, and
5 yeah, we've been denied this because of fear of
6 repercussions in any way for the payments that we
7 may make to doctors who may come to our
8 conferences. It costs about \$40,000 to run a
9 medical conference, and we have partnered with local
10 hospitals and done very well in reaching out to
11 doctors and nurses. So this is a sad consequence.

12 I guess everyone knows probably that
13 the heart disease rate in women is on the incline
14 again and that the gap between survival in women is
15 also widening. So we must look at gender specific
16 health care in medicine and include prevention as
17 the best course of action for women, because it is
18 safe, it is effective for women with heart disease,
19 and as I mentioned, we are the only organization
20 providing prevention programs.

21 Thank you very much for having me
22 here today. Are there any questions?

23 DR. BLANKS: So you focus on
24 prevention. And you run medical conferences --
25 well, you haven't run medical conferences --

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1 MS. ARKUS: In four years.

2 DR. BLANKS: And those medical
3 conferences were also focused on prevention?

4 MS. ARKUS: Prevention and medical

5 care for women in the area of heart disease and
6 treatments.
7 So we've had, for instance, Dr. Oz
8 speak at the Robert Wood Johnson University
9 Hospital, Dr. Mistretta, internationally known heart
10 surgeons and cardiologists at our conferences and
11 conventions, and Dr. Nieca Goldberg, Dr. Marianne
12 Legato, Dr. Correa-de-Araujo, Director of AHRQ.

13 DR. BLANKS: Is there -- do you
14 think that your focus on prevention has some effect
15 on your ability to receive funding?

16 MS. ARKUS: That's a good question.
17 We aren't the only organization that is trying to
18 implement prevention tactics into society and
19 institutionalize the message through high schools of
20 early intervention practices. We started Women's
21 Heart Week back in 1994, and we are considered by
22 the Government to be the leaders and the initiators
23 for the women's heart movement internationally since
24 1989.

25 Prevention needs to happen. We have
0137

1 costs that are going through the roof, and we know
2 that we can do much more in the way of prevention,
3 and the system's approach to wellness and
4 intervention is how we're approaching this.

5 As a nurse, I've designed many
6 medical information systems along the way, and I'm
7 working with Medicare and Medicaid to make this
8 happen for every citizen.

9 DR. BLANKS: Thank you.

10 MS. ARKUS: Thank you.

11 DR. BLANKS: Are there any people who
12 wish to speak who did not preregister?

13 (No response.)

14 DR. BLANKS: Well, we'd like to thank
15 you all again for coming and for your attention and
16 all of your participation and testimony today. And
17 there will be transcripts. There's a court reporter
18 here who made a transcript. So thank you very much
19 and safe travel.

20 (Hearing adjourned at 1:10 p.m.)
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1 C E R T I F I C A T E

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3 I, MARY ANN ADAMS, a Certified Court Reporter
4 and Notary Public of the State of New Jersey, do
5 hereby certify that the foregoing is a true and
6 accurate transcript of the proceedings as taken
7 stenographically by and before me at the time,
8 place, and on the date hereinbefore set forth.

9 I do further certify that I am neither of

10 counsel nor attorney for any party in this action, I
11 am unrelated to the parties involved in this action,
12 I have no financial interest and am not related to
13 an agent of or employed by anyone with a financial
14 interest, and that I am not interested in the event
15 nor outcome of this litigation.

16
17

18 _____
19 Notary Public of the State of New Jersey
20 I.D. NO. 372 - Expires August 2009
21 Certificate No. X101026

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Dated: December 6, 2007

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