THE DES ACTION VOICE
A FOCUS ON DIETHYLSTILBESTROL
Winter 2001 • #87

Direct-to-Consumer-Advertising: Who Benefits?

MASS media advertising for prescription drugs has exploded over the last several years in a phenomenon called Direct-to-Consumer-Advertising (DTCA). DES Action is involved in a collaborative group of grass roots health advocacy organizations from across the U.S. and Canada. All of us are concerned about the impact DTCA is having on our health care system.

A recent article published by the National Institute for Health Care Management (NIHCM)[1] painted a picture of just how effective this method is for increasing prescription drug sales. (All quotes below are from this article.) We at DES Action can only imagine what might have occurred had DES been advertised directly to consumers. There could be 50 million DES mothers rather than the 5 million we have today. Our awareness of the limitations of the FDA and the hazards of drugs that are rushed to market makes us wary of the huge promotional campaigns that launch ever more new drugs.

According to the NIHCM, spending on mass media advertising for prescription drugs reached $946 in the first four months of 2000—58 percent more than the $597 million spent during the first four months of 1999. "At that pace, DTC spending will break $2 billion in 2000."

"In 1999, DTC advertising accounted for 27 percent of the $6.6 billion pharmaceutical companies spent directly promoting their products to doctors and consumers. Mass media advertising was 22 percent of all direct promotion expenses in 1998, and 10 percent in 1995.

"The Food and Drug Administration (FDA) sparked the recent rapid growth in the mass media marketing of prescription drugs when, in 1997, it clarified rules pertaining to such ads. The action made it easier for companies to launch TV, print, and radio ad campaigns."

"Prescription drugs advertised directly to consumers are now the largest and fastest selling medicines. They contributed significantly to the 19% increase in pharmaceutical spending in 1999.

"Just 25 top-selling medicines promoted directly to consumers accounted for 40.7%—or $7.2 billion—of the overall $17.7 billion increase in retail drug spending in 1999.

"Recent studies project that prescription drug spending will increase on the order of 12 to18 percent per year through 2004. If that comes to pass, Americans will spend an estimated $218 to $254 billion on prescription drugs in 2005 and drug spending will represent as much as 14 percent of all health care spending, up from around 10 percent in 2000. The primary driver of this trend is the increase in the number of prescriptions being written, and the shift to newer, more expensive drugs.

"The growth of DTC advertising is altering the way prescription drugs are perceived. The ads send a strong signal that prescription drugs are just like any consumer product—soap, cereal, cars, snack foods, etc. Also, surveys indicate that while consumers bring a healthy skepticism to the claims made in prescription drug ads, they believe the information is approved by the government."

In fact, the ads are not approved in advance by the government and if the drug companies make unfounded or mislaiding claims the usual recourse is for the government to order them to remove the ads—after they have already aired.

The NIHCM points out that "numerous observers have raised concerns about whether mass media ads are inappropriately inducing demand for some new prescription medicines. They worry that people are beginning to ask their doctors for newer and costlier medicines when less expensive drugs may work just as well in many cases. There is also mounting concern that (a) mass media ads transform medicines into just another consumer product and (b) put pressure on drug makers to build "brand" name products that may have misplaced consumer allegiance."

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Update on DES Internet Listservs

by Sally Keely (aka "DESxposd")

THERE are now several DES e-mail lists.

DES Action members with e-mail access are invited to join the DES Action Listserv, DAL. The purpose of this listserv is to allow a direct e-mail link between DES Action and our members. This forum is primarily for information sharing, for instance: Legislative alerts, Press releases and news updates, Event announcements, e.g. DES Symposiums, Information from upcoming DES Action Voice newsletters.

This low volume list is a benefit of membership. Only current DES Action members may participate. To subscribe, send e-mail to Sally Keely, the list owner, at owner-DAL@perilpoint.com. Please include a statement that you wish to join DAL and the full name under which your current DES Action membership is listed. Note: this list has recently moved to a new server, so these are new subscribe directions. All 95 previous list members have already been transferred over to the new site. If you have any questions about the list, please contact Sally.

DES daughters should check out DES-L, the DES daughters listsev and online support forum at http://www.surrogacy.com/online_support/des/ To join the listserv, complete the online application and get ready to share support and information with 1000 other DES daughters!

DES sons will want to join the DES-Sons list for confidential discussions of issues related to DES exposure in males. This list was developed in conjunction with the DES Action. To subscribe send blank e-mail to des-sons-request@egroups.com. Direct questions to des-sons-owner@egroups.com.

The DES-Family list welcomes all DES-exposed, their family, and friends. To join, e-mail listserv@sact.com with only the command "subscribe des-family" (without the quotes) in the body of the message.

Charli@egroups.com can help if you have questions.

Lastly, announcing the newest DES related listserv, DES-Pregnancies. DES daughters who are pregnant, trying to conceive, or contemplating pregnancy are invited to join via the list website http://www.onelist.com/subscribe/despregnancies. You will need to register with onelist, if you aren't already. Contact ladonnakat@aol.com if you have trouble subscribing.

DES Action Affiliates and State Contacts

DES Action Affiliates

Each affiliate was created and nurtured by volunteers. Write to them if you want information or would like to volunteer.

DES Action USA National Office
610-16th Street #301
Oakland, CA 94612
desact@well.com

DES Sons Network
104 Sleepy Hollow Place
Cherry Hill, NJ 08003

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Mahwah, NJ 07430
Des3gen@aol.com

DES Action San Jose *(California)*
5835 Terrazo Court
San Jose, CA 95123

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DES Action Minnesota
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Coon Rapids, MN 55448

DES Action Pennsylvania
Box 398
Nescopeck, PA 18635

DES Action Washington
719 15th Avenue, East
Seattle, WA 98112

State Contacts

State contacts participate in national projects organized by DES Action. Contact the national office if you would like to find out about our national projects.

Arizona
Los Angeles, CA
San Diego, CA
Grand Rapids, MI
New Jersey
New Mexico
Ohio
Oregon
Texas

DES Action International

Australia
Belgium
Canada
England
France
Ireland
The Netherlands
New Zealand

Published quarterly by **DES Action USA**
610-16th Street #301, Oakland, CA 94612
ISSN 1522-0389

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Sphinx Graphics, Berkeley, CA

Printing:
Inkworks, Berkeley, CA

30-year Anniversary of Link Between DES and Cancer

DON'T miss this exciting event! DES Action will hold the first international colloquium on DES on April 2, 2001, in Washington, D.C. The DES Action International Colloquium: 30 Years of Discovery, Education, Science will bring together women who lead DES Action groups in Canada, England, Ireland, France, The Netherlands, Australia, and the U.S. to share strategies and to hear leading scientists and clinicians report research findings.

April, 2001 will mark thirty years since the publication of the landmark article "Adenocarcinoma of the Vagina: Association of Maternal Stilbestrol Therapy with Tumor Appearance in Young Women." This article, written by Dr. Arthur Herbst, et al, and published in the *New England Journal of Medicine*, linked cancer in young women to their in-utero exposure to DES and brought about an end to the use of DES during pregnancy.

The DES experience exploded the scientific concept of the placenta as an impenetrable barrier and has enlightened other important fields of science. Scientific knowledge about DES is pivotal to the growing field of endocrine disruptors and the understanding of estrogenic substances in our environment. Scientists, environmentalists, and health activists can all learn from the ongoing experiment represented by humans exposed to DES.

The long term nature of DES effects, which are still being studied today, serve as a potent and living reminder of the harmful consequences of inadequate drug promotion and distribution. The DES experience is more relevant than ever before in the new era of direct-to-consumer-advertising of pharmaceuticals.

This event takes place amidst renewed interest in the DES experience. Congress has funded a National DES Education Program currently in the planning stages at the Centers for Disease Control and Prevention. The DES Education Program will target health care providers and the public with current information about proper health care for DES-exposed patients.

The Colloquium is open to the public, and there is a registration fee of $65, which includes all conference materials, lunch, and a networking reception. For those able to stay, there will be a day of visits to legislator's offices on Tuesday, April 3. Visit with your Congressional representative and tell him or her why continued funding for DES research is so important!

For those traveling from out of town, we have reserved a block of rooms at the Hotel Lombardy, located at 2019 Pennsylvania Avenue, N.W., Washington, D.C. You can reserve a room by calling the hotel at 1-800-424-5486 or 202-828-2600. Tell the hotel that you are with group #8290. You must reserve your room by February 28, 2001.

For more information visit our website at desaction.org or call 1-800-DES-9288. If you wish to register today, send in the form included in this issue, along with your check.

Registration Form for DES Action International Colloquium

April 2, 2001 ■ Washington, D.C.

Name _____

Street address _____

City _____ State _____ Zip _____

Telephone _____ email _____

❑ Check or money order for $65 enclosed

Return to: DES Action
610-16th Street, Suite 301
Oakland, CA 94612

We will send you a confirmation packet upon receipt of your registration.

Book Notes

From Pat Cody

The Elusive Embryo: How Women and Men Approach New Reproductive Technologies, by Gay Becker. University of California Press, 2000. 320 pp. $17.95

THIS book is written for those who are thinking about using reproductive technology for pregnancy. It is not a consumer guide to those methods but rather a study of how couples are affected by these decisions and procedures. As such, this study by an anthropologist of over a hundred couples centers on their actions—not only going through treatments, but other actions like getting psychotherapy, counseling, alternative healing, and joining self-help groups like Resolve.

The powerful wish for a biological child has fueled a new industry whose costs mean the technology is restricted mainly to the middle and upper classes. And as this expensive technology advances, so do concerns about risks.

Drugs are used more aggressively, and as Becker writes, "Women and men were concerned about both short-term issues, such as side-effects and ovarian hyperstimulation, and long-term consequences, including multiple births and cancer." She also notes the non-medical risks such as emotional stress, financial burden, and the potential for multiple births, with their particular risks.

Because DES daughters often face reproductive difficulties,

"Men are usually reserved and reasonable and stuff, but I saw more pain openly demonstrated, talked about, and more tears in that experience with men than in any other experience I've ever had with other men. A man thinks that because his sperm doesn't have active flagella that he's not a human being? Not a man? Incredible! "

much of the material we have reported on these technologies covers the different kinds of treatments for women. We have not had studies like Becker's that write about either male infertility, such as DES sons may have, or the feelings that men have about using reproductive technologies where their partners have problems. One of the men Becker interviewed said, "It was really hard at first. I just hoped...a lot of sadness came with it, and it is what it is. And I felt that there's no choice. What I was really worried about feeling is that when you don't have children you feel pushed out somehow. And I felt that it was really hard to choose to do that (be childless). So then I felt like what would be right would be that neither of us should have biological kids and that we should adopt. I think it was also, for me, a sense of shame. I actually felt less than a man."

Later, Becker writes, "Men are outsiders to reproductive health. Although between 40 and 50 per cent of all infertility can be attributed at least in part to the male partner, there is little, if any, treatment for male infertility per se. Only recently have techniques been developed that can produce pregnancies with very few sperm...Such treatments not only are expensive but also involve invasive procedures that are carried out on women. As a result, men feel left out..."

A man who attended an infertility workshop told Becker: "It's sort of sad to see. I saw three men who doubted their masculinity because they were not able to father their child. I've never been in a group of men where there's been more raw emotion expressed than in that workshop. Men are usually reserved and reasonable and stuff, but I saw more pain openly demonstrated, talked about, and more tears in that experience with men than in any other experience I've ever had with other men. A man thinks that because his sperm doesn't have active flagella that he's not a human being? Not a man? Incredible! Others think he must not have a soul? He must not think he has any meaning beyond that. That's pretty sad."

The Elusive Embryo also covers the painful topic of the failure of reproductive technologies, coping with that realization, and getting on with life. Getting on can mean a number of things: using donor egg, donor sperm, surrogacy, adoption, or deciding to be a child-less family. Information about how reproductive technology—with its success and its failure—can affect the lives of

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women and men is a contribution to the literature on this important part of many people's lives.

20,125 Questionable Doctors. Each regional edition is $23.50 and can be ordered either by phone (1-877-747-1616) or from their web site: www.questionabledoctors.org.

THE Health Research Group of Public Citizen has published the latest edition of *20,125 Questionable Doctors*. It is a listing by 18 regions of physicians who have been sanctioned by their state medical boards. This valuable report covers doctors disciplined from January 1990 through December 1999. Almost all of the actions were for serious offenses but less than half had serious consequences. Most of the doctors disciplined for the most serious offenses: sexual abuse or misconduct, substandard care, incompetence or negligence, criminal conviction, mis-prescribing or over-prescribing, or substance abuse, were not required to stop practicing.

This would be a good book for your library to have. ■

Letters to the Editor

Dear Editor:

We were very pleased to see the review of our latest pamphlet, "How Safe are Our Medicines?" (Voice 85, Summer 2000). We believe that the information in the pamphlet is extremely relevant to people affected by DES worldwide and we would like to make it available to your readers. Anyone interested can obtain a copy free of cost from:

DES Action Canada
5890 Monkland Ave., # 203
Montreal, Que.
Canada H4A 1G2

Dear Editor:

The past 1-1/2 years my immune system has become so trashed. Through the Endometriosis Association I found out about a brilliant physician right here in Syracuse New York. Dr. Sherry Rogers is helping me to identify the causes of the thyroid problems, hypoglycemia, chronic infections, headaches, exhaustion, and so on. She asked an interesting question: "What do you believe was your 'original compromise' to your immune system?" Of course I focused in on the Lupron (hormone suppression) therapy and hysterectomy last year.

However, she picked up on the DES exposure in utero which I never really connected to my immune system problems to the extent that we do now. Dr. Rogers has written about 10 books. I encourage all DES daughters and sons to check out *The Environmental Illness Syndrome*. She picks right up on what exposure to chemicals and pharmaceutical products has done to so many of us. At the age of 43, I am on the road to some answers, finally. I wish the same to all of you.

Kathy Slattery
Baldwinsville, New York

TRANSCRIPT READY

A complete transcript of our October 1999 Symposium is now available from our national office for $10. It includes:

- DES Daughters and Sons: The Studies by Candy Tedeschi, RNC, OGNP
- Third Generation Research on Mice by Retha Newbold M.S.
- Menopause and Decisions by Phyllis Mansfield, Ph.D.

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Statement to the Food & Drug Administration

The Food & Drug Administration (FDA) held a hearing in December to examine the impact of DTCA. Deborah Hochanadel, Co-Director of the Massachusetts Breast Cancer Coalition, read a statement entitled "Putting People First" on behalf of our consumer collaborative. Here are some excerpts of the statement.

"I am here on behalf of a collaborative group of grass roots health advocacy organizations from across the United States and Canada. One of our activities is to act as a watchdog on federal health agencies such as the FDA to ensure that the public's interest is being served. None of our organizations accept funding from pharmaceutical companies.

Commissioner Henney has recently stated ("Challenges in Regulating Direct-to-Consumer Advertising," MSJAMA, 11/1/00) that the central question for the FDA surrounding DTCA is whether the advertisements provide consumers with information that empowers them to care for their health, or they mislead in a way that presents a public health hazard. We believe, based on our experience as advocates for women's health that, far too often, these ads mislead in a way that presents a threat to the public health and that the time has come for the FDA to put an end to direct-to-consumer advertising.

Those in favor of DTCA argue that the ads get people to see and discuss their health with their doctors. But in the current era of mangled care, when doctors have no time to spend with patients, let alone gather and evaluate independent information about new drugs, using ads to get people to talk to their doctors means that everyone—patients and doctors—ends up relying on the industry's information to make decisions and recommendations. And industry's information is not balanced information.

One striking example of the problems with how the FDA currently regulates DTCA is the experience that members of our collaborative group have had with DTC advertising of tamoxifen (Nolvadex®) to healthy women. As you know, the drug was first approved for healthy women at high risk of developing breast cancer in late 1998. Since then, members of our collaboration have complained to the FDA on three occasions about both television and print advertising of the drug by the drug's manufacturer, AstraZeneca. While the agency said it lacked authority to respond to our complaint on the T.V. ads, the FDA sustained two different complaints about print ads by the company, one in early 1999 and another the late summer of this year. The ads were found to overstate the benefits of tamoxifen and to understate the risks.

Because the FDA does not require prior clearance of the contents of ads, all of these complaints came after the fact, which means that millions of women were exposed to misleading advertising. The FDA's issuance of cease and desist orders come many months—most recently in our case six months—after a complaint is received. And, once a letter is issued, the advertiser has several more months in which to modify their ads. Corrective action may take a year or more, as it did in the case of the Astra-Zeneca ad. By the time the FDA acts on a misleading advertisement, the harm to the public has been done.

The FDA's authority and resources to deal with the problems caused by DTCA are severely limited. Since it appears to be the case that the FDA has neither the resources or the authority to properly protect the public against the dangers of DTCA, all of the groups that I represent here today urge the outright ban of direct-to-consumer advertising.

In any event, it is simply untenable that pharmaceutical companies can mislead the public with impunity, knowing that, by the time the FDA is both called upon and able to act, the damage will be irretrievabe.

If DTCA is allowed to continue, it must be done within a scheme that assures that companies either learn to operate within the DTCA guidelines issued by the FDA or be prohibited from engaging in DTCA. If the government is not prepared to institute an outright ban, we urge a "three strikes you're out" scheme that would prohibit a company that receives three cease and desist letters from the FDA regarding any drug or product/medical device over a seven year period from continuing to engage in DTCA.

If the government is not prepared to institute an outright ban, we also urge a restructuring of FDA resources so that DTC advertisements are reviewed

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Recommendation on listing steroidal estrogen as cause of cancer

EXPERTS consulted by the National Toxicology Program have recommended that steroidal estrogens be listed as a "known cause" of cancer in humans. DES is a steroidal estrogen and we welcome this recognition, which is long overdue.

The expert panel, meeting in Washington in December, considered a number of additions for a forthcoming Report on Carcinogens required by Congress to inform the public about potential cancer-causing substances. Other additions are wood dust and ultra-violet radiation.

The statement from the National Institute of Environmental Health Sciences (NIEHS), headquarters for the National Toxicology Program, reported:

"While panel members said these steroids have important medical uses and clear medical benefits, they have long been associated under certain conditions of use with a risk of uterine and breast cancers. The panel agreed 8 to 1 that these hormones cause an elevated risk and should be considered not merely as associated with increased cancer but as substances that are 'known to be a cause of human cancers.'

"The panel agreed 8 to 1 that these hormones cause an elevated risk and should be considered not merely as associated with increased cancer but as substances that are 'known to be a cause of human cancers.'"

"Estrogens occur naturally in women and to a lesser degree in men. They have important medical uses in hormone replacement therapies in post-menopausal women and for birth control. Their use has long been associated with a risk of uterine, endometrial and breast cancers. They are so labeled, panelists said, and doctors and women should weigh their known benefits against these risks. There was no suggestion by the panelists that medical use of estrogen be restricted or eliminated." ■

DIRECT-TO-CONSUMER from page 6...

before they are published, rather than after the fact. And we urge reorientation of FDA resources so that complaints that are made after the ads are published are more promptly resolved.

Last, but not least, if the government is not prepared to institute an outright ban, we believe that the FDA should require companies that run ads that violate the agency's guidelines to immediately run corrective advertisements in the same manner and markets, and for the same amount of time, as the misleading ad was in circulation.

Conflicts of Interest on FDA Advisory Committees

A great deal of attention has been paid in the media lately to the fact that so many of the scientists and researchers on FDA advisory committees have real or apparent conflicts of interest. The public's faith in the decisions made by the agency are undermined by these conflicts, and we believe they need to be addressed openly by the agency and corrected.

One aspect of this issue that is of particular concern to us relates to the possibility of conflicts of interest among consumer representatives to the advisory committees and among those who present testimony to the committees. Increasingly, groups that purport to represent a consumer view point are financed in whole or part by pharmaceutical companies or manufacturers of devices that come before the FDA for approval. The FDA should strengthen its requirement that all those who purport to represent a consumer point of view to the agency disclose whether they receive funding or other assistance from entities with economic interests at stake before they testify before the FDA. These conflicts of interest, like those involving the scientific and research community, need to be addressed and resolved by the FDA and we look forward to working with the agency to develop strategies for doing so." ■

[1] *Prescription Drugs and Mass Media Advertising, Research Brief, September 2000, NIHCM website, www.nihcm.org/DTCbrief.pdf*

Fran Fishbane

We extend our sympathies to the family of Fran Fishbane on her death in December. Fran, a DES mother, was one of the founders of DES Action and called the first meeting in April 1977 of other DES mothers and daughters from California, Connecticut, Illinois, Massachusetts, New Jersey and New York. Her tireless work on behalf of the DES exposed included getting the first, and best, state legislation for DES education and clinics in New York in 1978. That same year she traveled to Washington and with the help of Sidney Wolfe MD of the Public Health Research Group and medical writer Barbara Seaman, succeeded in getting Secretary Califano of the Dept. of Health, Education and Welfare (HEW, now HHS) to establish a Federal Task Force on DES. This group, which included these consumer representatives and leading DES medical specialists, met monthly and issued an important report in September 1978, the beginning of federal activity on behalf of DES education and research.

Fran helped with the early lawsuits by providing support and courtroom attendance and with the start of our DES Action VOICE newsletter. Her contributions have had a lasting effect on the success of DES Action.

23 YEARS OF

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