PUBLIC CITIZEN HEALTH RESEARCH GROUP

Health Letter

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20, 125 Questionable Doctors

In August, Public Citizen published *20,125 Questionable Doctors*, listing physicians who had been sanctioned by their state medical boards. 6,185 of these doctors had not been listed in previous editions. There was an excellent discussion of the new books on *Good Morning America* and the *CBS Evening News* and dozens of radio and television stations as well as many articles in publications such as *USA Today* and many local and regional newspapers.

20,125 Questionable Doctors lists doctors disciplined from January 1990 through December 1999 and is organized by state with 18 regional or state volumes available. Information came from all 50 state medical boards, the District of Columbia, the U.S. Department of Health and Human Services, the Drug Enforcement Administration, and the Food and Drug Administration. The 20,125 doctors had a total of 38,589 disciplinary actions taken against them.

Almost all of the disciplinary actions—90.6 percent—taken against the 20,125 doctors were for serious offenses (including substandard care, criminal conviction, substance abuse, sex-related offenses, misprescribing of drugs, providing false information to the state board, loss of hospital privileges or insurance fraud). Despite the gravity of these offenses, only 48 percent of the disciplinary actions were serious: revocation, suspension or surrender of license, or probation/restriction of license.

The majority of doctors who were disciplined for the five most serious offenses—sexual abuse or sexual misconduct; substandard care, incompetence or negligence; criminal conviction; misprescribing or overprescribing of drugs; or substance abuse—were not required to stop practicing even temporarily. Therefore, it is likely that they are still practicing and that their patients are unaware of their offenses.

Exemplifying the dangers posed to American patients of doctors who have committed serious offenses but have not been adequately disciplined and are still practicing are the following cases:

- Texas: Physician had sexual relations with at least 16 patients: Restrictions on license.
- Florida: Physician cut the wrong side of the skull in a brain operation: Fine, additional education.
- New York: Physician criminally convicted of assault with intent to murder his wife: Eight month suspension now on a 36 month probation.
- Missouri: Physician, during breast biopsy, administered high doses of drugs leading to cardiac arrest and death of the woman: Reprimand (same in TN. Based on MO action).
- California: Ob/gyn committed at least seven serious errors involving care during pregnancy or delivery of various patients: currently on 84-month probation. (New York revoked his license because of CA discipline for gross negligence and other negligence.)
- South Carolina: physician failed to respect the law by placing an amputated human foot in a crab trap: $3000 fine and reprimand.
- Virginia: Physician did artificial insemination using known HIV-positive semen, causing the woman to become HIV-positive; subsequently did this again on another patient: Reprimand.
- North Carolina: Physician operated on the wrong knee: Reprimand, additional education.
- Illinois: Physician failed to properly diagnose a breast lump which was found to be cancerous and failed to grant the patient's request for a

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biopsy of the lump in a timely manner: Fine, reprimand.

That these are not isolated examples can be seen from national data. Following are the percentages and numbers of physicians for each offense who did not have to stop practicing despite the offenses that they had committed:

Sexual abuse of or sexual misconduct with a patient: 547 doctors. Only 52.3 percent of these physicians had to stop practicing, even temporarily. 47.7 percent or 261 doctors were not required to stop.

Substandard care, incompetence or negligence: 3,215 doctors. Only 29.3 percent of these physicians had to stop practicing, even temporarily. 70.7 percent or 2,273 were not required to stop.

Criminal conviction (includes plea of guilty or no contest): 2,963 doctors. Only 39.2 percent of these doctors had to stop practicing, even temporarily. 60.8 percent or 1,802 were not required to stop.

Misprescribing or overprescribing of drugs: 1,318 doctors. Only 27.9 percent of these physicians had to stop practicing, even temporarily. 72.1 percent or 950 were not required to stop.

Substance abuse: 1,715 doctors. Only 32.4 percent of these doctors had to stop practicing, even temporarily. 67.6 percent or 1,159 were not required to stop.

As shown in Table A, of the 38,589 disciplinary actions reported by state boards or the federal government to Public Citizen (representing actions against 20,125 doctors), the majority (32,868 or 85.2 percent) of these were imposed by state medical boards. A description and statistical breakdown of the actions provided to Public Citizen by each state is provided in the "State by State Listings" section of each of the state or regional volumes. These counts represent the two most serious disciplinary actions for each sanction reported. Some sanctions included more than two actions against the doctors. These less serious actions are not included in these counts.

Table A: Disciplinary Actions by State and Federal Agencies

State/Federal Agency	Number of Actions	State/Federal Agency	Number of Actions
Alabama	366	Missouri	630
Alaska	161	Montana	97
Arizona	942	Nebraska	114
Arkansas	168	Nevada	151
California	2670	New Hampshire	117
Colorado	884	New Jersey	1472
Connecticut	440	New Mexico	145
Delaware	44	New York	2993
District of Columbia	242	North Carolina	523
DEA	***2462***	North Dakota	131
Florida	2746	Ohio	1484
FDA	***25***	Oklahoma	592
Georgia	855	Oregon	344
Hawaii	119	Pennsylvania	1230
Idaho	51	Rhode Island	176
Illinois	1390	South Carolina	389
Indiana	556	South Dakota	75
Iowa	526	Tennessee	409
Kansas	250	Texas	2035
Kentucky	595	Utah	218
Louisiana	505	Vermont	132
Maine	177	Virginia	567
Maryland	803	Washington	596
Massachusetts	586	West Virginia	419
Medicare	***3234***	Wisconsin	501
Michigan	1341	Wyoming	68
Minnesota	493	**Total**	**38,589**
Mississippi	298		

The federal agencies account for the remaining 5721 disciplinary actions imposed; 6.4 percent (2,462) were DEA sanctions in contested and uncontested cases, 8.3 percent (3,234) were fines and exclusions from the Medicare program, and 25 were restrictions placed on a physician's eligibility to participate as investigators in FDA experiments or to work for FDA-regulated companies.

Types of Disciplinary Actions and Offenses

The following tables provide a statistical national look at the types of disciplinary actions and the offenses for which they were taken.

Types of Disciplinary Actions Reported to Public Citizen

The most common type of state disciplinary action of those submitted to us was probation. States imposed probation 19.3 percent of the times (7,431 times) when practitioners were disciplined. They revoked licenses 7.9 percent of the time (3,045 times), suspended licenses 9.6 percent of the time (3,704 times), and accepted a doctor's surrender of his or her license 7.9 percent of the time (3,063 times). Cumulatively, only 9,812 or 25.4 percent of the actions against doctors listed in this report were ones which resulted in at least a temporary loss of ability to practice medicine (revocation, suspension and surrender). Most of the doctors who are listed in this book never had to stop practicing medicine and many

Table B: Disciplinary Actions Reported to Public Citizen: A Breakdown of the Types of Disciplinary Actions Contained in This Report

Disciplinary Action	Number	Percent
Probation	7431	19.3%
Suspension	3704	9.6%
Revocation	3045	7.9%
Fine	3708	9.6%
Surrender	3063	7.9%
Reprimand	3094	8.0%
Exclusion from the Medicare Program	3220	8.3%
Practice Restriction	2243	5.8%
Revocation, Surrender, Suspension of Controlled Substance License	2275	5.9%
Restriction of Controlled Substance License	1317	3.4%
Emergency Suspension	1231	3.2%
Education	1357	3.5%
Physician Monitoring	1251	3.2%
License Denial, Reinstatement or Nonrenewal	803	2.1%
Required to Enter an Impaired Physicians Program or Substance Abuse Treatment	266	0.7%
Other Actions	581	1.5%
Total Actions	**38589**	**100.0%**

Table C: Offenses for which Disciplinary Action was Taken*

Offense	Number	Percent
Criminal Conviction	2901	12.1%
Disciplinary Action Taken by Another State or Agency	7132	29.7%
Substandard Care, Incompetence, or Negligence	3184	13.2%
Misprescribing or Overprescribing Drugs	1302	5.4%
Substance Abuse	1683	7.0%
Professional Misconduct	2182	9.1%
Noncompliance with a Board Order	1274	5.3%
Noncompliance with a Professional Rule	2075	8.6%
Practicing without a License	420	1.7%
Practicing without a Controlled Substance License	70	0.3%
Providing False Information to Medical Board or Other Health Agency	417	1.7%
Sexual Abuse of or Sexual Misconduct with a Patient	536	2.2%
Physical or Mental Impairment	472	2.0%
Hospital Privilege Loss or Restriction	236	1.0%
Insurance or Medicare/Medicaid Fraud	72	0.3%
Falsifying/Altering Medical Records	38	0.2%
Overcharging	34	0.1%
Exceeding Professional Limitations	14	0.1%
Total Records With Offense Cited	**24042**	**100.0%**

** Frequencies and types of violations cited by states or federal government for disciplinary actions. Includes only those actions for which an offense was reported and for which we had a corresponding term in our database.*

more who had suspensions are once again practicing. It is not likely that many of their patients are aware of these actions, see Table B.

Offenses for which Disciplinary Action was Taken

The reason an action was taken—the offense—was provided by state and federal authorities for 24,042 of the records in our database. For a number of offenses, more than one action was taken. In 7,132 cases, the stated reason for the listed actions was "disciplinary action taken by another state or agency," leaving 16,910 offenses with specific details as to the nature of the offense. For 15,310 of these offenses or 90.6 percent of them, the offense was one of the five discussed previously—substandard care, incompetence or negligence, criminal conviction, substance abuse, misprescribing or over prescribing of drugs or sex-related offenses—or another serious offense such as providing false information, loss of hospital privileges or fraud, see Table C.

Disciplinary Actions Taken Against Doctors Cited for Sexual Abuse of or Sexual Misconduct with a Patient.

Of the 547 different doctors who were disciplined for sexual abuse of or sexual misconduct with a patient, there were 302 actions (81 revocations, 46 surrenders, 130 suspensions plus 45 emergency suspensions) which required those doctors, at least temporarily, to stop practicing medicine. Switching from actions to doctors, there were 286 doctors (52.3 percent) who were, at least temporarily, removed from practice by license suspension, surrender or revocation. But this means that at least 47.7 percent of doctors (261 doctors) were allowed to continue practicing, their behavior probably unknown to most if not all of their patients. It is likely that other doctors, especially those whose licenses were only suspended temporarily, are once again practicing medicine, see Table D, pg. 4.

Table D: Disciplinary Actions Taken Against Doctors Cited for Sexual Abuse of or Sexual Misconduct with a Patient

Action	Number	Percent
Revocation	81	10.3%
Surrender	46	5.9%
Suspension	130	16.6%
Emergency Suspension	45	5.7%
Probation	189	24.1%
Fine	77	9.8%
Other Actions	217	27.6%
Total Actions	**785**	**100.0%**

Disciplinary Actions Taken Against Doctors Cited for Substandard Care, Incompetence or Negligence

Of the 3,215 different doctors who were disciplined for substandard care, incompetence or negligence, there were 987 actions (315 revocations, 244 surrenders, 338 suspensions plus 90 emergency suspensions) which required those doctors, at least temporarily, to stop practicing medicine. Switching from actions to doctors, there were 942 doctors (29.3 percent) who were, at least temporarily, removed from practice by license suspension, surrender or revocation. But this means that at least 70.7 percent of doctors (2,273 doctors) were allowed to continue practicing, their behavior probably unknown to most if not all of their patients. It is likely that other doctors, especially those whose licenses were only suspended temporarily, are once again practicing medicine, see Table E.

Disciplinary Actions Taken Against Doctors Cited for Criminal Convictions

Of the 2,963 different doctors who were disciplined because of a criminal conviction, there were 1,363 actions (563 revocations, 159 surrenders, 491 suspensions plus 150 emergency suspensions) which required those doctors, at least temporarily, to stop practicing medicine. Switching from actions to doctors, there were 1,162 doctors (39.2 percent) who were, at least temporarily, removed from practice by license suspension, surrender or revocation. But this means that at least 60.8% of doctors (1,801 doctors)

Table E: Disciplinary Actions Taken Against Doctors Cited for Substandard Care, Incompetence or Negligence

Action	Number	Percent
Revocation	315	6.8%
Surrender	244	5.3%
Suspension	338	7.3%
Emergency Suspension	90	2.0%
Probation	1181	25.6%
Practice Restriction	359	7.8%
Fine	809	17.6%
Reprimand	491	10.7%
Other Actions	779	16.9%
Total Actions	**4606**	**100.0%**

were allowed to continue practicing, their behavior probably unknown to most if not all of their patients. It is likely that other doctors, especially those whose licenses were only suspended temporarily, are once again practicing medicine, see Table F.

Table F: Disciplinary Actions Taken Against Doctors Cited for Criminal Convictions

Action	Number	Percent
Revocation	563	16.2%
Surrender	159	4.6%
Suspension	491	14.1%
Emergency Suspension	150	4.3%
Probation	587	16.9%
Fine	203	5.8%
Other Actions	1319	38.0%
Total Actions	**3472**	**100.0%**

Disciplinary Actions Taken Against Doctors Cited for Misprescribing or Overprescribing Drugs

Of the 1,318 different doctors who were disciplined because of misprescribing or overprescribing drugs, there were 378 actions (96 revocations, 85 surrenders, 155 suspensions plus 42 emergency suspensions) which required those doctors, at least temporarily, to stop practicing medicine. Switching from actions to doctors, there were 368 doctors (27.9 percent) who were, at least temporarily, removed from practice by license suspension, surrender or revocation. But this means that at least 72.1 percent of doctors (950 doctors) were allowed to continue practicing, their behavior probably unknown to most if not all of their patients. It is likely that other doctors, especially those whose licenses were only suspended temporarily, are once again practicing medicine, see Table G.

Table G: Disciplinary Actions Taken Against Doctors Cited for Misprescribing or Overprescribing Drugs

Action	Number	Percent
Revocation	96	5.0%
Surrender	85	4.4%
Revocation, Surrender, or Suspension of Controlled Substance License	171	8.9%
Suspension	155	8.1%
Emergency Suspension	42	2.2%
Probation	486	25.2%
Restriction of Controlled Substance License	211	11.0%
Fine	200	10.4%
Education	141	7.3%
Other Actions	338	17.6%
Total Actions	**1925**	**100.0%**

Disciplinary Actions Taken Against Doctors Cited for Substance Abuse

Of the 1,715 different doctors who were disciplined because of substance abuse, there were 611 actions (71 revocations, 111 surrenders, 293 suspensions plus 136 emergency suspensions) which required those doctors, at least temporarily, to stop practicing medicine. Switching from actions to doctors, there were 556 doctors (32.4 percent) who were, at least temporarily, removed from practice by license suspension, surrender or revocation. But this means that at least 67.6 percent of doctors (1,159 doctors) were allowed to continue practicing, their behavior probably unknown to most if not all of their patients. It is likely that other doctors, especially those whose licenses were only sus-

Table H: Disciplinary Actions Taken Against Doctors Cited for Substance Abuse

Action	Number	Percent
Revocation	71	2.9%
Surrender	111	4.5%
Revocation, Surrender, or Suspension of Controlled Substance License	116	4.7%
Suspension	293	11.8%
Emergency Suspension	136	5.5%
Probation	741	29.9%
Restriction of Controlled Substance License	143	5.8%
Fine	43	1.7%
Required to Enter an Impaired Physician Program or Substance Abuse Treatment	161	6.5%
Other Actions	665	26.8%
Total Actions	**2480**	**100.0%**

pended temporarily, are once again practicing medicine, see Table H.

Conclusions

This country's system for ensuring medical quality needs to be made much stronger. We suggest several avenues towards improvement. Most states need to strengthen their medical practice statutes, restructure their medical boards, and dramatically increase both funding and staffing. Most states should also establish programs to audit and weed out bad doctors so that patient injuries can be prevented rather than simply reacted to.

The total number of serious state disciplinary actions against physicians decreased from 2,803 reported for 1995 to 2,696 in 1999 for a nationwide rate of 3.50 serious actions per 1,000 physicians. A difference greater than 10-fold exists between Alaska, the state with the highest rate (10.34 per 1,000), and Delaware, with the lowest rate, (0.96).

It is clear that state-by-state performance is spotty. Only one of the nation's 15 largest states, Ohio, is represented among those 10 states with the highest disciplinary rates, as it also was in 1996, 1997 and 1998. Other large states such as, New York, Michigan and California (14th, 19th and 20th respectively in 1999) have shown improvement from 40th, 49th and 37th in 1991. But other large states such as Texas, Pennsylvania, Massachusetts and Illinois (34th, 36th, 39th and 43rd in 1999) have not done very much doctor discipline for many of the last 10 years. It is not unreasonable to estimate that a nationwide average rate of at least 10 serious disciplinary actions per 1,000 doctors can be attained (the number was 3.50 in 1999) since, in most years, one or more states (Alaska, in 1999) actually takes this many actions. This would amount to 7,703 serious disciplinary actions a year, far in excess of the 2,696 serious disciplinary actions in 1999. If this had occurred, there would have been 5,007 more serious disciplinary actions that year—almost three times the number of actions, which actually were taken.

Recommendations

Congress should require cooperation and routine data-sharing between state medical boards, Medicare Peer Review Organizations, state Medicaid agencies, the Drug Enforcement Administration and hospitals in catching and sanctioning malfeasant physicians.

The National Practitioner Data Bank, which began collecting information on questionable doctors in September 1990, should be opened to the public. This change will require legislation. Although there have been Congressional hearings on this topic in 2000, there is not any evidence that Congress has enough guts to take on the AMA.

The Drug Enforcement Administration should routinely tell the public and pharmacists which doctors' controlled substances prescription licenses it has pulled or restricted.

State medical boards should be required to promptly make public all their disciplinary actions and the offenses for which their actions were taken, and to regularly distribute lists of actions to consumers, the press, and other health care consumer organizations. In addition, boards should publicly disclose information they have concerning final hospital disciplinary actions and malpractice payouts.

In the past two years, many medical boards have started putting varying degrees of disciplinary information on their web sites (for a report on the status of these sites—with grades A to X for completeness—visit our web site at *http://www.citizen.org/hrg/publications/1506.htm*). Unfortunately, most states either have no web site with disciplinary information or an inadequate amount of information about this important topic. Combined with the fact that only slightly more than half of the people in this country have access to the Internet, this means that probably 75 percent of the people in this country do not have Internet access to an adequate amount of this information. It is inexcusable that all states do not have detailed information about actions and offenses about every doctor who has been disciplined, including a copy of the board's order spelling out the details as to why the action was taken.

Product Recalls

July 13—August 9, 2000

DRUGS & DIETARY SUPPLEMENTS

This chart includes recalls from the Food and Drug Administration (FDA) Enforcement Report for drugs, dietary supplements and medical devices, and Consumer Product Safety Commission (CPSC) recalls of consumer products.

The recalls noted here reflect actions taken by a firm to remove a product from the market. Recalls may be conducted on a firm's own initiative, by FDA request, or by FDA order under statutory authority. A Class I recall is a situation in which there is a reasonable probability that the use of or exposure to the product will cause serious adverse health consequences or death. Class II recalls may cause temporary or medically reversible adverse health consequences. A Class III situation is not likely to cause adverse health effects. If you have any of the drugs noted here, label them *Do Not Use* and put them in a secure place until you can return them to the place of purchase for a full refund. You can also contact the manufacturer. If you want to report an adverse drug reaction to the FDA, call (800) FDA-1088. The FDA web site is *www.fda.gov*.

This month the FDA issued five Class I recalls for dangerous dietary supplements. Since the passage of the Dietary Supplement Health and Education Act (DSHEA) of 1994, the authority of the FDA to protect the public from untested dietary and herbal supplements has been severely restricted. Because herbal and dietary supplements are, for all practical purposes unregulated, their quality and content are unknown and the use of any of these products may present a significant risk to your health while not necessarily being effective.

Name of Drug or Supplement; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Dianolyn (tm) Capsules, OTC oral dietary supplement, in bottles of 30; Class I; Unapproved new drug—This product contains the prescription diabetes drug glyburide (DIABETA, MICRONASE) that is not listed on the label. The use of this product could cause a dangerous lowering of blood sugar.	Lot #0914 EXP 10/02; 10,788 boxes distributed nationwide; Phyytos Nutri-Pharma, Corona, California. Recalled by Diabetic Capital (U.S.) LLC, Alhambra, California
Dimelstat (tm) Capsules, OTC oral dietary supplement in bottles of 60; Class I; Misbranding: This product contains the prescription diabetes drug glyburide (DIABETA, MICRONASE) that is not listed on the label. The use of this product could cause a dangerous lowering of blood sugar.	Lot #0915 EXP 10/01; 953 bottles distributed in Alabama, California, Connecticut, Florida, Maryland, New Jersey, New Mexico, Washington and Canada; Phyytos Nutri-Pharma, Corona, California. Recalled by SciQuest Lab, Inc., Brea, California
Dream On (sleep aid), OTC liquid in 16-ounce plastic bottles, marketed and used to enhance sexual activity, improve physical performance, reduce stress, as a sleep aid and widely used as a recreational drug; Class I; Unapproved new drug product: contains GBL (Gamma- Butyrolactone). GBL is also used as a "date rape" drug. As of August 1999, GBL and related supplements have been linked to at least 122 serious illnesses reported to the FDA, including three deaths.	All lot numbers; 1,000 bottles distributed nationwide; Undetermined manufacturer. Recalled by J.N.G. Sports Distributors, Bloomburg, Pennsylvania
Tricana (tm) Capsules (Metabolic Hormone Analogue), 1g, in bottles of 90, OTC, marketed as a dietary supplement to treat obesity; Class I; Unapproved new drug product—Contains tiratricol (Thyroid Hormone). The excessive use of Thyroid Hormone may cause serious health consequences including heart attacks and strokes.	Lot Number 00201 EXP 02/02; 11,359 bottles distributed nationwide; Undetermined manufacturer. Recalled by J.N.G. Sports Distributors, Bloomburg, Pennsylvania
Tricana (tm) Capsules, 1 mg, in units of 90, Rx for the treatment of obesity and reducing the problem areas of fat; Class I; Unapproved new drug.	All lot codes; 33,203 bottles distributed nationwide; Thermo-Life International, San Carlos, California

Name of Drug or Supplement; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Alcohol Prep Antiseptic Pad in Lovenox (r) ContinuCare (tm) Program AT HOME KITS; Class II; Lack of assurance of sterility for the Clinipad Corporation manufactured alcohol prep pads.	All lot numbers; Firm estimated that 300 kits remained on international market at time of recall; Aventis Pharmaceutical Products, Collegeville, Pennsylvania. Component Manufacturer Clinipad Corporation, Rocky Hill, Connecticut
Artificial Tears, Polyvinyl Alcohol 1.4%, in 1-fluid ounce bottles, OTC ophthalmic solution, under the following labels: Optopics, Rite Aid, Eckerd, and Nex; Class II; Lack of assurance of sterility	Lot #8I101 EXP 9/01; 19,755 bottles distributed nationwide; Miza Pharmaceuticals, Inc., doing business as Optopics Laboratories, Fairton, New Jersey
Aspirin Tablets, 325 mg, in units of 2, 100, and 300, Rx under the following labels: Pharmacist Formula (2 tablets); Albertson (100 count); and Target (300 count); Class III; Dissolution failure (24 month stability)	Lot #8M00476 EXP 10/01; 47,832 10-tablet bottles 9,276 300-count bottles and 5,424 boxes 100 tablet blisters were distributed nationwide; Leiner Health Products, Inc., Kalamazoo, Michigan
Atropisol(r) Atropine Sulfate Ophthalmic Solution 1%, 1 mL, Rx indicated for the treatment of inflammatory conditions and also for refraction; Class III; Product labeled with incorrect expiration date	Lot Numbers and EXP dates: W102, W103 4/00, W104, W105 5/00, W106 8/00, X2091 2/00, X2092 3/01, X2093, X2094, X2095 8/01, X2096, X2097, X2098, X2099 9/01; 14,665 units distributed nationwide; OMJ Pharmaceuticals, San German, Puerto Rico. Recalled by CIBA Vision Corporation, San German, Puerto Rico
Estratab (r) (Esterified Estrogens Tablets), 2.5 mg, in bottles of 100, Rx intended for hormone replacement; Class III; Tablets did not meet friability specification	Lot #90654 EXP 6/01; 2,282 bottles distributed nationwide; Solvay Pharmaceuticals, Inc., Baudette, Minnesota
Glyburide Tablets, (micronized), 6 mg, in 100-tablet bottles, Rx indicated as adjunct to diet to lower blood glucose in patients with non-insulin-dependent diabetes mellitus (type II) whose hyperglycemia cannot be satisfactorily controlled alone; Class II; Blend uniformity failure	Lot #ST2343A EXP 9/00; 8,407 bottles distributed nationwide; MOVA Pharmaceuticals Corporation, Caguas, Puerto Rico
IBU (r) Tablets (Ibuprofen), 800 mg, in 500-count bottles, Rx nonsteroidal anti-inflammatory agent; Class III; Product exceeds impurity specification at 18-month stability (4-isobutylacetophenone)	Lot #20692 EXP 11/00; 9,279 bottles distributed nationwide; BASF Corporation, Shreveport, Louisiana
JPI Jones Daniels Pharmaceuticals Levoxyl (Levothyroxine Sodium Tablets), 75 mcg (0.075 mg), Rx, packaged in unit-dose strips 10/10-tablet strips per box; Class III; Mislabeling—The milligram conversion on the unit blisters is incorrectly declared as 0.75 mg.	Lot #6221 EXP 02/01; 440 10/10-tablet strip boxes distributed nationwide; Daniels Pharmaceuticals, St. Petersburg, Florida. Recalled by Jones Pharma, Inc., St. Louis, Missouri
Lanoxin Tablets, 0.125 mg, in bottles of 30 and 100, Rx oral cardiotonic indicated for the treatment of mild to moderate heart failure and for the control of ventricular response rate in patients with chronic atrial fibrillation; Class III; Tablets do not meet thickness specification and therefore may be subpotent	Lot Numbers: 9355140, 0006075, and 9354174; 105 bottles distributed nationwide; Glaxo Wellcome, Inc., Zebulon, North Carolina. Recalled by Allscripts, Inc., Libertyville, Illinois
MediGel H (Topical Hydrocortisone Hydrogel), 1% Hydrocortisone, in 4-ounce plastic bottles, OTC; Class III; Super-potent	Lot #LMQ; 228 bottles distributed nationwide; Henley Healthcare, Inc., Sugarland, Texas
Pannaz (tm) Tablets, antihistamine-decongestant (Phenylpropanolamine HCl, 75 mg, Chlorpheniramine Maleate 8 mg, Methscopolamine Nitrate 2.5 mg), in 100-tablet bottles, Rx; Class III; Lack of complete manufacturing process validation	Lot #V6337A01 EXP 5/02; 9,493 bottles distributed nationwide; Anabolic Laboratories, Inc., Irvine, California

DRUGS & DIETARY SUPPLEMENTS *cont.*

Name of Drug or Supplement; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Triazolam Tablets, 0.125 mg and 0.25 mg, Rx product taken orally as sleeping aid, under the labels of Par and Qualitest; Class III; Individual impurity specification failure	Numerous lot numbers; 15,696 units distributed nationwide; Alphapharm Pty Ltd., Carole Park, Old, Australia. Recalled by Par Pharmaceutical, Inc., Spring Valley, New York
Vasosulf (r) Ophthalmic Solution (sulfacetamide sodium 15%-Phenylephrine Hydrochloride 0.125%), Rx indicated for treatment of conjunctivitis, corneal ulcer, and other superficial ocular infections, and an adjunctive in systemic sulfonamide therapy of trachoma; Class III; Failure to revalidate new manufacturing specifications	Code X1095 EXP 1/01, Y1104 EXP 7/00, X1105 EXP 2/01; 19,872 units distributed nationwide; OMJ Pharmaceuticals, San German, Puerto Rico. Recalled by CIBA Vision Corporation, San German, Puerto Rico
Vicoprofen (r) Tablets (hydrocodone bitartrate 7.5 mg and ibuprofen 200 mg), in 500-count bottles, Rx; Class III; Misbranded—Some bottles have partially illegible lot numbers and/or expiration dates	Lot #0000060685 EXP 10/01; 3,475 bottles distributed nationwide; Knoll Pharmaceutical Company, Whippahy, New Jersey

MEDICAL DEVICES

Device recalls are classified in a manner similar to drugs, Class I, II or III, depending on the seriousness of the risk presented by leaving the device on the market. Contact the company for more information. You can also call the FDA's Device Recall and Notification Office at (301) 443-4190. To report a problem with a medical device, call 1-800-FDA-1088. The FDA web site is *http://www.fda.gov.*

Name of Drug or Supplement; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Infant Apnea Monitors; Class II; Electrical circuit on the display printed circuit board can become damaged	Healthdyne SmartMonitor series Catalog Numbers - 900S, 900S-02, 900S-02-01, 900S-02-04, 900S-02-07, 900SL, 970S, 970S-02, 970S-02-01, 970SE, 970SE-02, 970SE-02-04, 970SE-02-07. Note: serial numbers relate to year and month. A-L=January- December; first numerical character defines year, 5-9=1995-1999. This recall involves all type 3A and 3B SmartMonitors Infant Apnea Monitors manufactured between 12/1/95 to 1/15/00; 28,000 units distributed nationwide and internationally; Respironics, Inc., Marietta, Georgia

CONSUMER PRODUCTS

Contact the Consumer Product Safety Commission (CPSC) for specific instructions or return the item to the place of purchase for a refund. For additional information from the Consumer Product Safety Commission, call their hotline at 1-800-638-2772. The CPSC web site is *http://www.cpsc.gov.*

Name of Product; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Baby Walkers (Recall to Repair); Babies can lose their lower teeth when the teeth are caught in parts of the three-spoke steering wheels. Also, on some walkers, the telephone could break apart, releasing small parts and posing a choking hazard	Model number 45701, 45701A or 45701B Mobile "4 Wheelin" Walkers, shaped like cars; 170,000 sold nationwide from April 1998 through April 1999; Safety 1st Inc., Canton, Massachusetts (800) 964-8489
Backpack Baby Carriers; Small infants can shift to one side, slip through leg openings and fall	Gerry® TrailTech™ with plastic frames; 111,000 sold nationwide from January 1996 through July 2000; Hufco-Delaware Co., Miamisburg, Ohio (800) 881-9176

CONSUMER PRODUCTS *cont.*

Name of Product; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Caterpillar Toys; Young children can choke on small balls attached to these toys	Wiggle Waggle pull toy shaped like a caterpillar that plays songs; 1 million sold nationwide from May 1998 through June 2000; Child Guidance, a division of JAKKS Pacific Inc., New York, New York (877) 586-1006 www.jakkspacific.com/recall.html.
Coleman Gas Grills; Sharp edge on metal heat shield below control panel of the grill can cause lacerations to the hands, wrists or arms	Series numbers 2000 or 3000; 86,000 sold nationwide from January through April 2000; The Coleman Co., Witchita, Kansas (877) 846-1070 (Call for free repair kit) www.bbqhq.com/aboutus/recall.htm
Doll Feeding Sets; Doll bib in the set has snaps that detach, presenting a choking hazard to young children	Set consists of bib with pink and blue baby cupids, plastic baby food jar with pink top and label reading "Love My Baby Baby Food"; 700,000 sold at Dollar Tree Stores nationwide during December 1999; Dollar Tree Stores Inc., Chesapeake, Virginia (800) 876-8077
Glass and Metal Oil Burning Candles; Glass can shatter, creating a fire hazard	Rectangle and circular shapes with black metal frame; 16,000 sold at Target stores nationwide from January through May 2000; Target Corporation, Minneapolis, Minnesota (800) 440-0680
Gun Locks; Due to manufacturing discrepancy, the two halves of some gun locks can be manually separated without a key, giving children and others unauthorized access	"Master Lock Tough Under Fire" imprinted on the lock's black rubber pad; 752,000 sold nationwide at Walmart, Kmart, Gander Mountain and Sports Authority from June 1999 through July 2000; Master Lock Co., Milwaukee, Wisconsin (800) 944-1380 http://www.masterlock.com/recall.html
Juice Extractors; Filter and lid can break apart, and project metal and plastic into the air, causing injuries to nearby consumers	Betty Crocker model BC-1480; 229,000 sold nationwide at Kmart stores from September 1992 through June 1995; Appliance Co. of America LLC, Great Neck, New York (800) 872-1656
Nightlights; Faceplate can be broken off, exposing wiring and posing shock and electrocution hazards	"Elmo Nitelights" "Henson" and "the first years" are imprinted on the back; 123,000 sold nationwide from July 1997 through March 2000; The First Years Inc., Avon, Massachusetts (800) 533-6708
Pacifier Clips; Metal clip and the small rivet that attaches the clip to a small, stuffed animal on the pacifier holder can break apart easily, exposing babies to small parts which poses a choking and aspiration hazard	Magic Years® Novelty Pacifier Buddy Clips; 12,700 sold nationwide from September 1999 through June 2000; Rashti & Rashti Inc., New York, New York (800) 4-RASHTI
Plastic Teether Toys; Teether can easily pull apart and expose small pieces	Whoozit(r) Touch and Teethe™, with item number WZ-450; 22,000 sold nationwide from February through May 2000; Manhattan Group LLC, Minneapolis, Minnesota (800) 541-1345
Play Tables (xylophone mallets); Mallet that comes as part of table set can be lodged into the throats of young children, posing a choking hazard	"Stand-Up 'N Play Tables" measuring 14 inches long, 14 inches wide, 13 inches high. Table includes telephone, clicking dial, spinner, push-button squeaker, rolling ball, spinning gears, xylophone and mallet, shapes, and a shape sorter; 124,000 sold nationwide from March 1996 through March 1999; Shelcore Inc., Somerset, New Jersey (800) 777-0453
Plush Toys; Stuffing of toys can contain sewing needles and sharp metal pieces	Multi-colored, plush fabric sorter box with six shapes and four multi-colored stacking shapes that graduate from large to small. All shapes rattle, crackle or squeak; 19,000 shape sorter toys and 12,000 stacking toys sold nationwide at Gymboree and Play & Music Stores, and Gymboree web site from November 1998 through April 2000; The Gymboree Corp., Burlingame, California (800) 222-7758

CONSUMER PRODUCTS *cont.*

Name of Product; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Propane Cylinders; 10% could be overfilled, which can cause them to release flammable propane gas unexpectedly, posing a risk of fires and explosions	"Prefilled Propane Xchange" or "PPX"® gas grill cylinder; 100 sold or exchanged at The Home Depot or Meijer's stores in Detroit, Michigan area from July 17 through July 19, 2000; AmeriGas Propane L.P., Valley Forge, Pennsylvania (888) 428-9779
Swim Masks; Glass lens can break into sharp pieces, causing lacerations	"Splash Club" swim masks for children; 85,550 sold at Kmart and Super Kmart stores nationwide from February to July 2000; Kmart Corp., Troy, Michigan (800) 63K-MART
Toaster Ovens; Toasters could short circuit, causing electrical shocks and fires and heating elements can break, causing the glass door to shatter	Welbilt model number TR660 with rotisserie and griddle; 7,000 sold from January through May 2000; Appliance Co. of America, Great Neck, New York (800) 872-1656

OUTRAGE, *from page 12*

human experiments. In a gross commercialization of this practice, one large family practice group advertised its "computerized patient data base of 40,000 patients" to HECs and others running clinical trials as one from which "We can actively recruit patients for any study...." According to Richard Friedman of Cornell University in the British journal, the *Lancet*, "In the USA, monetary incentives have spawned a whole industry of private physicians who don't necessarily have any experience in research or with protocols in the specialty areas in which they're testing." These private entities "push patients through trial after trial," with little concern for what happens to them afterwards. The result is "stop-gap" medicine for vulnerable patients who can't afford treatment any other way, he says.

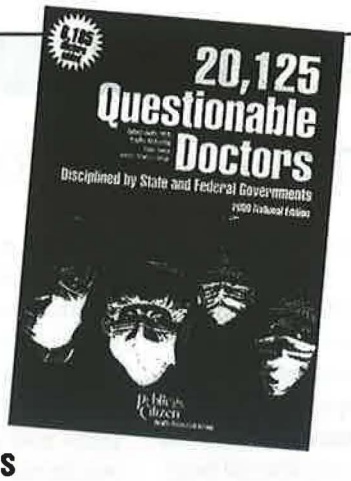
Drug companies can increase the likelihood of a drug's success by using exclusion criteria to, as one investigator told the Inspector General's office, "enrich trials with patients who are most likely to benefit." One way to accomplish this is to exclude patients who are currently on medication to treat their condition or even those who have been on medication in the past. Remaining for inclusion are patients known in the industry by the double entendre "naive" subjects. These prized subjects are hard to locate but, according to the Inspector General's Report, can often be found among the uninsured or in foreign countries. Many researchers told the Inspector General's staff that drug companies are increasingly looking abroad for such subjects. The Report points out that the number of new foreign investigators in the FDA's database grew from 988 in the 1990-1992 period to 5,380 in the 1996-1998 period. I have seen one industry magazine (*Scrip*) advertisement directed toward possible drug industry customers by the world's largest HEC, North Carolina-based Quintiles—with offices in 31 countries all over the world which boasted of their ability to recruit foreign experimental subjects. The ad promised that Quintiles can "even help you tap the vast drug-naive patient populations of China, Korea and other emerging markets."

There is little question that these issues fall squarely within the topic of this conference: *Human Subject Protection and Financial Conflict of Interest*. The interposition of an increasing number of for-profit entities, beyond the pharmaceutical industry itself, between human experimental subjects and the ethical performance of appropriate clinical trials poses a serious threat to human subject protection. There is, in a real sense, a double conflict of interest. First, the primary allegiance of many of these entities is toward their owners or stockholders, a financial conflict of interest which expands on the more narrow definition focused on by most of the participants in this conference. Second, the paying clients of the HECs—the pharmaceutical companies—present another conflict of interest. The more quickly the studies are performed, the more favorable the outcome in terms of utility for drug approval, the more the drug company will be pleased and will be more likely to return for more business. Possibly lost in this duet of conflict of interest with HEC stockholders and drug company clients are the patients.

Because the HECs are not affiliated with academic medical centers, they cannot use the Institutional Review Boards (IRBs) to seek approval of their protocols and informed consent sheets. Instead, they use a whole new breed of for-profit Independent Review Boards (curiously, also called IRBs). These entities have the same double conflict of interest as the HECs described above.

Rather than yielding to the dominant spirit of this conference as articulated by FDA Commissioner Dr. Jane Henney "financial conflict of interest is now an inherent part of the process" and merely seeking to manage it, to try to "make it nice," I propose the following:

Abolish, by Federal regulation, for-profit human experimentation corporations (HECs) and the other for profit-entities which partner with them such as for-profit IRBs as prima facie examples of irreparable conflict of interest which cannot ultimately be managed and need to be declared off-limits for the purpose of doing experiments on drugs or other products for FDA approval.



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Human Experimentation for Profit

The following remarks are excerpted from a talk on August 16th by Dr. Sidney Wolfe at a meeting jointly sponsored by the Food and Drug Administration (FDA), the National Institutes of Health, the Centers for Disease Control and Prevention and the Department of Health and Human Services (HHS) entitled: *Conflict of Interest and Human Subject Protection*.

The pharmaceutical industry itself is and has always been primarily a business with a fiduciary duty to its stockholders to produce revenue. Fortunately, there has also been room for some important advances in the form of new pharmaceutical products. But the majority (80-90 percent) of clinical research for the purposes of assessing efficacy and safety of drugs used to be done in academic medical centers whose primary purposes were and still are medical education and providing health care services.

In its recent, disturbing investigation, *Recruiting Human Subjects: Pressures in Industry-Sponsored Clinical Research*, the HHS Inspector General's Office describes "the transformation of clinical research into a traditional business model." Parallel to the shift to this business mind set, with an estimated 62 percent of clinical research studies being done by for-profit companies in 1999, the often highly unethical and possibly illegal patient recruitment practices documented in the Inspector General report appear to be increasing rapidly. The rise of separate (from the drug companies themselves) for-profit Human Experimentation Corporations (HECs) has introduced new techniques for rapidly recruiting patients. Without either teaching or routine medical care responsibilities, HECs can do clinical research much more quickly and efficiently than academic medical centers. In addition, because they lack an institutional base of patients, HECs are much more likely to recruit experimental subjects in private doctors' offices and foreign countries than are academic medical centers.

The number of private practice-based investigators has grown from 3,153 in 1990 to 11,588 in 1995, an increase of almost four-fold concomitant with the increasing domination of HECs in human experimentation. The vulnerability of a doctor's own patients to be persuaded to become an experimental research subject because of their trust in their doctor, combined with signing bonuses which the doctor pockets for the referral sets up a toxic situation where some doctors are literally selling their own patients into

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