



Criminalizing the Seriously Mentally Ill: Two Decades Later

In 1992, Public Citizen’s Health Research Group, in cooperation with the National Alliance for the Mentally Ill (NAMI), published *Criminalizing the Seriously Mentally Ill: The Abuse of Jails as Mental Hospitals*.¹ The study reported that 7.2 percent of all jail inmates at that time were seriously mentally ill and that the problem was getting worse. The study also detailed the problems that occur when seriously mentally ill individuals are incarcerated, problems both for these individuals and for jail personnel. (The reprint of the November 1992 *Health Letter* article summarizing that study appears on page 3.)

Given that almost two decades have passed since the report was released, we thought it would be useful to review what has happened regarding this issue, especially during the last 10 years.

The numbers

The number of seriously mentally ill individuals in jails has increased sharply during the last two decades. As state psychiatric hospitals have increasingly been shut down, more individuals with schizophrenia and bipolar disorder wander the streets untreated. Many commit minor crimes, such as shoplifting, but a few commit major crimes, including homicides, thus landing in jail. By 2000, the percentage of jail inmates with serious mental illnesses had increased to at least 10 percent and has now risen to 20 percent or higher.

2006

- The U.S. Department of Justice reported that 24 percent of inmates in county jails and 15 percent of inmates in state prisons were psychotic.
- In Atlanta, “the number of inmates being treated for mental illness has increased 73.4 percent between 1999 and 2006. ... When the Georgia Mental Health Institute ... closed in the late 1990s, the jail’s population of inmates with mental illness increased dramatically.”²

2007

- The Missouri Department of Corrections estimated that 20 percent of prisoners “suffered from a mental illness,” double the rate in 1997. In Boone County, “at least 30 percent of the jail population” was said to be mentally ill.
- In Virginia, the Roanoke County sheriff claimed that “between 25 percent and 30 percent of his inmates suffer from mental illness.” One woman with schizophrenia had been there so many times that when she was asked by a psychiatrist who her best friend was, she named a deputy at the jail.³

2008

- In the Denver, Colo., metro area, 20 percent of jail inmates have “a serious mental illness. ... Seriously ill inmates spend 5½ times longer in jail ... and housing them takes a \$34.4 million annual bite out of the counties’ tight budgets.”⁴

As state psychiatric hospitals have increasingly been shut down, more individuals with schizophrenia and bipolar disorder wander the streets untreated.

2009

- A study of jails in Maryland and New York reported that 15 percent of male and 31 percent of female inmates had a “serious mental illness.”
- In the Corrections Center of Northwest Ohio, 25 percent of the inmates “were on psychotropic medications,” which cost “nearly half of the medical budget.”⁵

2010

- In Florida’s Broward County, “23 percent of the jail system’s population [are] on psychotropic drugs,” and they remain in jail “eight times longer than other inmates.” In Miami’s Dade County Jail, “an average of 600 inmates have mental illness serious enough to be segregated from the general

see **CRIMINALIZING**, page 2

In This Issue

Criminalizing the Seriously Mentally Ill: The Abuse of Jails as Mental Hospitals.....	3
RECALLS.....	7
OUTRAGE!.....	12

PUBLIC CITIZEN
Health Letter

JULY 2011 • Vol. 27, No. 7

Editor

Sidney M. Wolfe, M.D.

Managing Editor

Cynthia Williams

Contributors

Sidney M. Wolfe, M.D.
Michael A. Carome, M.D.
E. Fuller Torrey, M.D.

Graphic Designer

Erin Hyland

Public Citizen President

Robert Weissman

The Health Research Group was co-founded in 1971 by Ralph Nader and Sidney Wolfe in Washington, D.C., to fight for the public's health and give consumers more control over decisions that affect their health.

Annual subscription rate is
\$18.00 (12 issues).

Material in the *Health Letter* may not be reprinted without permission from the Editor. Send requests, subscription and address changes to:

Health Letter

1600 20th St., NW,
Washington, D.C. 20009

Copyright © *Health Letter*, 2011
Published monthly by Public Citizen's
Health Research Group
All rights reserved. ISSN 0882-598X

CRIMINALIZING, from page 1

population," double the number from ten years ago.⁶

2011

- In Connecticut, 18 percent of the prison population was "receiving mental health treatment." The medical cost for severely mentally ill male prisoners was "about \$12,000" per year, compared to \$4,780 for non-mentally ill prisoners.
- In Iowa, the Black Hawk County sheriff said that "more than 60 percent of the inmates in his jail are mentally ill. ... 'Every year, those numbers get worse.'"⁷

A 2010 survey reported that nationally "there are now more than three times more seriously mentally ill persons in jails and prisons than in hospitals." In states such as Arizona and Nevada, the difference was more than nine-fold. The three largest de facto psychiatric inpatient facilities in the country are the county jails in Los Angeles, Chicago and New York. In fact, there is not a single county in the U.S. in which the public psychiatric inpatient unit holds as many mentally ill persons as the county jail holds.⁸

County jails ill equipped to handle mentally ill inmates

The problems caused by the increasing number of mentally ill inmates in jails and prisons are legion. In Florida's Orange County Jail, the average stay for all inmates is 26 days; for mentally ill inmates, it is 51 days. In New York's Rikers Island Jail, the average stay for all inmates is 42 days; for mentally ill inmates, it is 215 days. The main reason mentally ill inmates stay longer is that many find it difficult to understand and follow jail and prison rules. In one study, jail inmates were twice as likely (19 percent versus 9 percent) to be charged with facility rule violations. In a county jail in Virginia, 90 percent of assaults on deputies were committed by mentally ill inmates.⁹

The jailing of mentally ill inmates

also results in major management problems because of their impaired thought processes.

- A deputy at Mississippi's Hinds County Detention Center said: "They howl all night long. If you're not used to it, you end up crazy yourself." One inmate in this jail was described as an inmate who "tore up a damn padded cell that's indestructible, and he ate the cover of the damn padded cell. We took his clothes and gave him a paper suit to wear, and he ate that. When they fed him food in a Styrofoam container, he ate that. We had his stomach pumped six times, and he's been operated on twice."
- Mentally ill prisoners are also victimized much more frequently than non-mentally ill prisoners. According to a 2007 prison survey, "approximately one in 12 inmates with a mental disorder reported at least one incident of sexual victimization by another inmate over a six-month period, compared with one in 33 male inmates without a mental disorder." Among female mentally ill inmates, it was three times higher than among male mentally ill inmates.¹⁰

The way forward

In the past two decades, the nation's jails have indeed become the new mental hospitals. The situation has progressively worsened, a trend that continues. In our 1992 report, we made 13 recommendations to improve the situation. Significantly, only one of those recommendations — an increase in jail diversion programs using mental health courts — has been implemented. Until we reconfigure our public mental illness treatment programs and focus more resources on individuals with serious mental illnesses, this travesty will continue, to the detriment of mentally ill individuals and their families, as well as jail personnel. ♦

see **CRIMINALIZING, page 6**

Criminalizing the Seriously Mentally Ill: The Abuse of Jails as Mental Hospitals

The following article originally appeared in the November 1992 Health Letter.

In September 1992, Public Citizen’s Health Research Group and the National Alliance for the Mentally Ill jointly released a report on seriously mentally ill people in our nation’s jails, titled *Criminalizing the Seriously Mentally Ill: The Abuse of Jails as Mental Hospitals*. This project grew out of findings from our previous studies ranking state programs for the seriously mentally ill. (See “Care of the Seriously Mentally Ill: A Rating of State Programs,” *Health Letter*, October 1990.) The following summary is adapted from this 152-page report, which drew from a nationwide survey of jails (most run by cities and counties), and from a survey of mentally ill persons who have been in jail and their families.

The seriously mentally ill in jail: Then and now

Two hundred years ago, the most common “treatment” for serious mental illness was jail. Thousands of people suffering from what would now be diagnosed as schizophrenia, manic-depressive illness or other severe disorders were brutally locked away and forgotten. It was not until the first half of the 19th century that Dorothea Dix and other reformers waged a fight to transfer thousands of these individuals to psychiatric hospitals. By late in the century their battle was won: The 1880 census found that only 0.7 percent of jail inmates — 1 in 148 — were seriously mentally ill.

Today we’re back to the 1830s. A nationwide survey of 1,391 local jails, which together hold 62 percent of all jail inmates, has revealed the unimaginable: 7.2 percent of jail inmates — more than 1 in every 14 — suffer from serious

Table 1. Percentage of Jails Holding Mentally Ill Without Criminal Charges, by State/District (1992)

Rank	State	Percent
1/6	New Jersey	0.0
1/6	Rhode Island	0.0
1/6	Pennsylvania	0.0
1/6	Delaware	0.0
1/6	District of Columbia	0.0
1/6	Connecticut	0.0
7	Maryland	6.7
8/9	North Carolina	11.3
8/9	Illinois	11.3
10	West Virginia	11.8
11	Massachusetts	12.5
12	Virginia	13.7
13	Minnesota	13.9
14	New York	14.3
15	Wisconsin	15.4
16	Florida	16.3
17	Alabama	18.2
18	Ohio	19.2
19	California	19.6
20/21	Hawaii	20.0
20/21	Vermont	20.0
22	Nebraska	22.7
23/25	Washington	25.0
23/25	Georgia	25.0
23/25	New Hampshire	25.0
26	Michigan	25.5

Rank	State	Percent
27	Iowa	25.9
28	Oregon	26.9
29	Arizona	27.3
30	Louisiana	27.8
31	Tennessee	30.3
32	Idaho	30.8
33	Indiana	34.5
34	Colorado	35.5
35	Utah	35.7
36	North Dakota	36.4
37	Texas	37.6
38	Missouri	38.0
39/40	Maine	40.0
39/40	Oklahoma	40.0
41	South Carolina	40.7
42	Kansas	47.4
43/44	Arkansas	50.0
43/44	Nevada	50.0
45	South Dakota	53.8
46	New Mexico	62.5
47	Wyoming	64.3
48	Montana	68.7
49	Alaska	75.0
50	Mississippi	75.9
51	Kentucky	81.1
	U.S.	28.9

mental illness. This represents a 10-fold increase since 1880.

Each day, more than 30,700 seriously disturbed individuals serve time in American jails. Put another way, each year more than 11 million days are spent by such people in jails. These figures do *not* include mentally ill inmates in state or federal prisons. Our jails have once again become surrogate mental hospitals, recriminalizing the seriously mentally ill.

Why are so many seriously mentally ill people in jail?

The underlying cause of the growth in numbers of seriously mentally ill individuals in jail is a profound failure of the public mental health system. State psychiatric hospitals were virtually emptied during “deinstitutionalization,” which started in the 1960s and peaked in the 1970s.

see [JAILS](#), page 4

JAILS, from page 3

State and local governments failed to provide necessary follow-up services to these newly released patients, and as a result, thousands of seriously mentally ill individuals now find themselves held in jail — many on no criminal charges at all, most on trivial charges and only a relatively few on serious charges.

No criminal charges

Twenty-nine percent of jails surveyed hold seriously mentally ill individuals without any criminal charges against them. These people are often jailed because no facilities are available to respond to psychiatric emergencies. Their only “crime” is their illness.

Incarceration of the seriously mentally ill with no charges against them persists even where categorically prohibited by state law. It is far more common in most of the 17 states where laws explicitly allow it under certain circumstances: Alaska, Colorado, Iowa, Kansas, Kentucky, Minnesota, Mississippi, Montana, Nebraska, New Mexico, North Dakota, Ohio, South Dakota, Texas, Utah, Virginia and Wyoming. Jailing mentally ill people without criminal charges is also significantly more likely in states with poor outpatient psychiatric services, as rated by our 1990 report *Care of the Seriously Mentally Ill: A Rating of State Programs*. Five states — Connecticut, Delaware, New Jersey, Pennsylvania and Rhode Island — and the District of Columbia had no such people in jail, according to this report.

Trivial charges

Most seriously mentally ill individuals are criminally charged when arrested. However, the vast majority of their “crimes” are trivial, typically, misdemeanors that are often just manifestations of their mental illness, such as disorderly conduct, trespassing and drunkenness. They are jailed — when what they really need is treatment — for lack of anything else to do with them. This is known as the “criminalization” of mental illness and makes no more sense than punishing

Table 2. Mental Health Resources Available to Jails (in 1992 report)

	Number of Jails	Percent
No Mental Health Resources	288	20.7
None or Emergency Room	179	12.9
Jail Nurse	68	4.9
Jail Doctor	52	3.7
Mental Health Resources	417	30.0
24-Hour or On-Call Access	178	12.8
Psychiatrist	153	11.0
Counselor/Therapist	130	9.3
Psychologist	86	6.2
Social Worker	55	4.0
Psychiatric Nurse	25	1.8
Mental Health Worker	16	1.2
Undefined Access to Mental Hospital or Mental Health Center	556	40.0
Other	130	9.3

Two hundred years ago,
the most common
“treatment” for serious
mental illness was jail. ...
Today we’re back
to the 1830s.

people with Alzheimer’s disease or brain tumors for the behavioral problems caused by their disease.

Serious charges

A small minority of seriously mentally ill people are charged with serious crimes. The perpetrators are frequently individuals whose mental illness has been left untreated. Their crimes are an unfortunate but predictable consequence of the breakdown of the public mental health system.

What happens to seriously mentally ill people in jail?

Jail is no place for the seriously mentally ill. Their psychiatric and medical problems often deteriorate without timely access to treatment. Despite the best efforts of some jail officials, many mentally ill people are cruelly abused by other inmates, enduring torment, beatings and rape, and exposed to deadly diseases,

including tuberculosis and AIDS. Some seriously mentally ill inmates take their own lives rather than continue to suffer.

While some jails provide adequate psychiatric services to mentally ill inmates, many do not. More than one-fifth of jails have no access to mental health services of any kind. Eighty-four percent of jails (five out of six) report that corrections officers receive three hours or less of training in the special problems of the mentally ill, and some receive none at all.

What happens to seriously mentally ill people upon release?

Many jail officials do not know what happens to seriously mentally ill individuals after release. Forty-six percent of jails do not know whether their former inmates subsequently receive outpatient psychiatric services. Jails that do know report that just 36 percent receive initial outpatient treatment.

About one-third of seriously mentally ill individuals who serve time in jail are or have been homeless. For these people, life can be even worse on the streets, and many soon return to jail. The cycle of mental hospital, streets

see [JAILS, page 5](#)

JAILS, from page 4

and jail is a way of life for thousands of seriously afflicted Americans.

What are the social costs of jailing seriously mentally ill people?

The current institutional shuffle is extremely costly, both for the seriously mentally ill and for society. Police officers who must respond to mental health emergencies have less time to spend fighting crime. Jail cells that hold seriously mentally ill people are not available for the confinement of real criminals. Overcrowding due to criminalization of mental illness results in reduced sentences for people who are genuine threats to society.

Investing in comprehensive outpatient treatment and programs to keep seriously mentally ill people out of jail will put more police on the streets and more criminals behind bars. A humane system of comprehensive outpatient psychiatric treatment will also save millions of dollars in jail and inpatient hospital expenses. It is the only logical choice for Americans who want to reduce crime, conserve resources and provide basic care for fellow citizens in need.

Is the problem getting worse?

Sixty-nine percent of jails — including a majority in 41 states — report seeing more or far more inmates with serious mental illnesses now than 10 years ago, and indications are that in the absence of aggressive new action, the problem will continue to get worse.

Worst county and state awards

The award for the county with the worst record for jailing the mentally ill belongs to Flathead County in northwestern Montana. For the past 20 years, only the local jail — and not the local general hospital or for-profit psychiatric hospital — has routinely accepted psychiatric emergency

The underlying cause of the growth in numbers of seriously mentally ill individuals in jail is a profound failure of the public mental health system.

admissions. Mentally ill individuals are kept in the “soft cell,” a barren, padded room with a grate in the floor for a toilet. Meals are passed through a slot in the door. *It is little different from rooms used to house the mentally ill in 1950, 1920 — or 1820.*

The award for being the worst state goes to Kentucky. The most shameful aspect of Kentucky’s system is its two-class character: most mentally ill people with health insurance or money go to private psychiatric hospitals, while those without resources go to jail — whether or not criminal charges are lodged against them. A staggering 81 percent of Kentucky jails report holding uncharged seriously mentally ill individuals.

Best programs

Some communities have risen to the challenge of caring for these seriously mentally ill people. Exemplary efforts include “jail diversion” programs (to keep the seriously mentally ill out of jail) in Norristown, Pa.; Memphis, Tenn.; and Seattle, Wash. Emphasis is on training of law-enforcement officers.

Despite the fact that most seriously mentally ill inmates should not be in jail at all, some jails do their best to provide humane care. Comprehensive psychiatric services are provided in jails in Madison, Wis.; Ann Arbor, Mich.; and other cities where local leaders recognize the need.

Recommendations

The U.S. needs fundamental reform of its public mental health system to emphasize high-quality outpatient services for people with severe mental illness. *At a minimum*, we recommend the following steps to guarantee basic rights and humane treatment to jailed seriously mentally ill individuals:

- States with laws permitting jails to

be used for emergency detention of people with mental illness who are not charged with any crime should immediately amend such laws to prohibit this practice, and those not doing so by Jan. 1, 1995, should lose eligibility for federal mental health block grants.

- Jail diversion programs should be set up to minimize the number of those with serious mental illness who end up in jail.
- All inmates with serious mental illness should be evaluated by a mental health professional within 24 hours of incarceration. Ongoing psychiatric services, including medication if necessary, should be available in the jail on a timely basis.
- Jail inmates with serious mental illness who need medication and have no insight into their illness should be medicated involuntarily if necessary to protect themselves and others.
- In counties or states where mental health authorities have failed to set up jail diversion programs, and where significant numbers of individuals with serious mental illness continue to be jailed on misdemeanor charges or without charges, the Department of Mental Health should be required to transfer funds to the Department of Corrections.
- When inmates with serious mental illness are released from jail, follow-up psychiatric care as needed should be mandated by the courts as a condition of parole or probation.
- Corrections officers who work in jails and police officers in the community should receive training on serious mental illnesses.

see JAILS, page 6

JAILS, from page 5

- All state or federally supported training programs for mental health professionals should require trainees to spend a minimum of six hours in on-site training in jails.
- Mental health professionals should be required to provide two hours of pro bono service per week to public mental health facilities, including jails, as a condition of licensure.
- Increased resources under the Protection and Advocacy Act of

1986 should be devoted to assisting jailed individuals with serious mental illness.

- Relevant federal and state statistical reporting systems should be modified to reflect the presence of seriously mentally ill people in jails.
- At each jail in the U.S. there should be a standing mental illness committee with representation from the jail administration, the local Department of Mental Health, the local public psychiatric inpatient unit, and the local

chapter of the National Alliance for the Mentally Ill.

- Local chapters of the National Alliance for the Mentally Ill should closely monitor what is happening in local jails and, when reform efforts fail, seek class-action relief through the courts.

To view the entire *Criminalizing the Seriously Mentally Ill: The Abuse of Jails as Mental Hospitals* publication, visit <http://www.citizen.org/criminalizingtheseriouslymentallyill>. ♦

CRIMINALIZING, from page 2

***Criminalizing the Seriously Mentally Ill: Two Decades Later* references**

¹ Torrey EF, Stieber J, Ezekiel J, Wolfe SM, et al. *Criminalizing the Seriously Mentally Ill: The Abuse of Jails as Mental Hospitals*. Washington, D.C.: National Alliance for the Mentally Ill and Public Citizen's Health Research Group; 1992.

² James DJ, Glaze, LE. *Mental Health Problems of Prison and Jail Inmates*. Washington, D.C.: Bureau of Justice Statistics, U.S. Department of Justice; 2006; Simmons A. Prisons see more inmates requiring mental health care. *Gwinnett (Ga.) Daily Post*. July 30, 2006.

³ Hermes A. Boone County struggles to meet mental health care needs for inmates. *Missourian*. December 17, 2007; Hammack L. Jail can offer temporary refuge for those suffering from mental illness. *Roanoke (Va.) Times*. October 15, 2007.

⁴ Schrader A. Better to aid mentally ill outside of jail, report says. *Denver Post*. April 19, 2008.

⁵ Steadman HJ, Osher FC, Robbins PC, et al. Prevalence of serious mental illness among jail inmates. *Psychiatric Services*. 2009;60:761–765; Satija N. Toledo area jails facing growing numbers of the mentally ill: inmate influx is attributed to fewer hospitals. *Toledo Blade*. August 30, 2009.

⁶ Mozingo J. Jailing the ill. *Miami Herald*. November 15, 2007.

⁷ Chedekel L. Prisons grappling with more mentally ill inmates. *New Haven Independent*. March 22, 2011; Geary M. Mentally-ill inmates fill Black Hawk County Jail. *Eastern Iowa News Now*. April 3, 2011.

⁸ Torrey EF, Kennard AD, Eslinger D, et al. *More Mentally Ill Persons Are in Jails and Prisons Than Hospitals: A Survey of the States*. Arlington, Va.: Treatment Advocacy Center; 2010.

⁹ Criminal Justice/Mental Health Consensus Project. *Fact Sheet: Mental Illness and Jails*. New York: Council of State Governments; http://consensusproject.org/downloads/fact_jails.pdf; Turner C. Ethical issues in criminal justice administration. *American Jails*. January/February 2007; Butterfield F. Study finds hundreds of thousands of inmates mentally ill. *New York Times*. October 22, 2003; Connolly K. Mentally ill increasing strain on US prison system. *BBC News*. February 22, 2011: <http://www.bbc.co.uk/news/world-us-canada-12532538>.

¹⁰ Fields G. No way out: trapped by rules, the mentally ill languish in prison. *The Wall Street Journal*. May 3, 2006; Parker M. Mentally ill jailed, awaiting therapy. *Clarion Ledger* (Jackson, Miss.). August 16, 2010; Wolff N, Blitz CL, Shi J. Rates of sexual victimization in prison for inmates with and without mental disorders. *Psychiatric Services*. 2007;58:1087–1094.

Product Recalls

May 26, 2011 – June 29, 2011

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

DRUGS AND DIETARY SUPPLEMENTS

Recalls and Field Corrections: Drugs – Class I

Indicates a problem that may cause serious injury or death

Best Enhancer Capsules, 150 mg, 1-count blister pack packaged in a 24-count display carton and 12-count bottles. Volume of product in commerce: 22,116 single blister packs and 418 12-count bottles. Marketed without an approved NDA/ANDA: FDA lab analysis found that the Best Enhancer supplement contains sulfoildenafil, an analogue of Sildenafil, an FDA-approved drug used in the treatment of male erectile dysfunction, making these products unapproved new drugs. Lot #: all lots. Planet Advertising Group Inc. d/b/a Drive Total Energy.

Man Up Now, dietary supplement capsule, 450 mg, 1-capsule blister pack, 2-capsule blister pack, 3-capsule blister pack, 6-count bottle, 12-count bottle, 30-count bottle. Volume of product in commerce: Unknown. Marketed without an approved NDA/ANDA; product found to contain sulfoildenafil, an analogue of Sildenafil, a prescription drug used for treatment of male erectile dysfunction. Lot #: all lots with the following UPC numbers: 753182111018, 753182057552, 753182111056, 753182111032, 753182111025, 753182057569, 753182111001, 753182057590 and 753182057583, ongoing. Body Action.

Recalls and Field Corrections: Drugs – Class II

Indicates a problem that may cause temporary or reversible health effects; unlikely to cause serious injury or death

Alendronate Sodium Tablets, USP, 10 mg, 30-count bottles. Volume of product in commerce: 4,651 bottles. Labeling: label error on declared strength. Bottle labeled as Alendronate Sodium Tablets 10 mg was filled with Alendronate Sodium 5-mg tablets. Lot #: JKJ2441A. Sun Pharmaceuticals Ltd.

Azithromycin Tablets, 250 mg, 6 x 1 blister packs. Volume of product in commerce: Unknown. CGMP deviations: Firm's laboratory investigations were not performed in accordance with strict adherence to the FDA Guidance for Industry — Investigating Out-of-Specification Test Results for Pharmaceutical Production. Lot #: 01A173. Teva Pharmaceutical Industries.

Avalide (Irbesartan-Hydrochlorothiazide) Tablets, 150/12.5 mg, 300/12.5 mg, 300/25 mg. Volume of product in commerce: 1,495,124 bottles and 324,792 sample packs. CGMP deviations: crystallization. This voluntary recall is based upon Bristol-Myers Squibb's determination that tablets from Avalide 150/12.5 mg, 300/12.5 mg and 300/25 mg lots, manufactured by Bristol-Myers Squibb, may contain small quantities of the less soluble crystalline Form B of the irbesartan active ingredient. Crystalline Form A is the intended form of irbesartan in the finished drug product. While all lots released to the market conformed with dissolution specifications, the presence of Form B of the irbesartan crystalline structure may result in slower dissolution. A thorough review of the global postmarketing safety database has not revealed evidence of a signal suggesting reduced efficacy. However, we (FDA) cannot definitively exclude this possibility at this time. Lot #: Multiple lots affected. Contact your pharmacist. Bristol-Myers Squibb Manufacturing Co.

Azithromycin Tablets, 500 mg, 30-count bottle. Volume of product in commerce: Unknown. CGMP deviations: Firm's laboratory investigations were not performed in accordance with strict adherence to the FDA Guidance for Industry — Investigating Out-of-Specification Test Results for Pharmaceutical Production. Lot #: 02A016. Teva Pharmaceutical Industries.

Calan SR (Verapamil Hydrochloride) Sustained-Release Caplets, 120 mg, 100-count bottle. Volume of product in commerce: 4,927 bottles. Marketed without an approved NDA/ANDA: The recall is being initiated because the Pfizer manufacturing site in Caguas, Puerto Rico, is currently not an approved site for manufacturing Calan SR 120 mg. Lot #: C100010. Pfizer Pharmaceuticals LLC.

Clonazepam Tablets, USP, 2 mg, 100-count bottle. Volume of product in commerce: 28,033 bottles. Low tablet weight: tablets may not conform to weight specifications. Lot #: 28C004, expiration date 05/2012. Teva Pharmaceutical Industries.

DRUGS AND DIETARY SUPPLEMENTS (continued)

Glyburide and Metformin Hydrochloride Tablets, USP, 2.5 mg/500 mg, 100-count bottle. Volume of product in commerce: Unknown. CGMP deviations: Firm's laboratory investigations were not performed in accordance with strict adherence to the FDA Guidance for Industry — Investigating Out-of-Specification Test Results for Pharmaceutical Production. Lot #: G31120, expiration date 02/2011. Teva Pharmaceutical Industries.

Glyburide and Metformin Hydrochloride Tablets, USP, 5 mg/500 mg, 100-count bottle. Volume of product in commerce: Unknown. CGMP deviations: Firm's laboratory investigations were not performed in accordance with strict adherence to the FDA Guidance for Industry — Investigating Out-of-Specification Test Results for Pharmaceutical Production. Lot #: 16G319, 16G321, expiration date 07/2011. Teva Pharmaceutical Industries.

Glyburide and Metformin Hydrochloride Tablets, USP, 5 mg/500 mg, 500-count bottle. Volume of product in commerce: Unknown. CGMP deviations: Firm's laboratory investigations were not performed in accordance with strict adherence to the FDA Guidance for Industry — Investigating Out-of-Specification Test Results for Pharmaceutical Production. Lot #: 16G275, 16G276, 16G277, expiration date 03/2011; 16G330, 16G346, 16G347 and 16G348, expiration date 08/2011. Teva Pharmaceutical Industries.

Methylprednisolone Tablets, USP, 4 mg, 100-count bottle. Volume of product in commerce: Unknown. Impurities/degradation: Product is being recalled due to the potential of not meeting the Impurity C

specification through the product shelf life. Lot #: 309686, expiration date 10/2011; 312821, 702008, expiration date 02/2012. Barr Laboratories Inc.

Methylprednisolone Tablets, USP, 4 mg, 21-count blister pack. Volume of product in commerce: Unknown. Impurities/degradation: Product is being recalled due to the potential of not meeting the Impurity C specification through the product shelf life. Lot #: 313026, 313526, 314411, 313161, 313784, 314412, expiration date 04/2011; 307956, 308308, 308963, expiration date 08/2011; 310370, 310479, expiration date 10/2011; 311211, 312074, 311263, 312293, expiration date 02/2012; 314524, 315734, expiration date 05/2012; 316926, 317387, expiration date 07/2012. Barr Laboratories Inc.

Plavix (Clopidogrel Bisulfate) Tablets, 75 mg, 30-count bottles. Volume of product in commerce: 105,576 bottles. Chemical contamination: presences of 2,4,6-tribromoanisole. Lot #: 0F61121, expiration date 06/2013. Bristol-Myers Squibb Manufacturing Co.

Topamax (Topiramate) Tablets, 100 mg, 60-count bottles; bottles of 60 are sold as bottles or cases of 48. Volume of product in commerce: 57,624 bottles. Chemical contamination. Lot #: 0KG110, expiration date 06/2012; 0LG222, expiration date 09/2012. Jansen Ortho LLC.

Tretinoin Capsules, 10 mg, 100-count bottle. Volume of product in commerce: 1,880 bottles. Impurities/degradation: May not conform to impurity specifications. Lot #: 702305, expiration date 08/2011. Teva Pharmaceuticals USA Inc.

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 CPSC, call its hotline at (800) 638-2772. The CPSC website is www.cpsc.gov. Visit www.recalls.gov for information about FDA recalls and recalls issued by other government agencies.

Name of Product; Problem; Recall Information

Abilitations aDOORable Swing Bar. A welded eye hook on the swing bar can break, posing a fall hazard. Sporting King Co. Ltd., at (888) 388-3224 or www.sportime.com.

Ab Straps Exercise Equipment. The plastic buckle on the ab straps can break, posing a fall hazard to consumers. Harbinger Fitness, at (800) 729-5954 or www.harbingerfitness.com.

Adventure Playsets Wooden Swing Sets. The wood in the posts of the fort sections on the swing sets can weaken due to rotting, posing a fall hazard. Adventure Playsets, at (877) 840-9068 or www.recall.adventureplaysets.com.

Air Exchangers. The motor in the air exchangers can overheat, posing a fire hazard to consumers. Venmar Ventilation Inc., at (866) 441-4645 or www.venmar.ca.

American Girl Crafts Pearly Beads and Ribbon Bracelets Kit. The surface coating on some of the beads contains excessive levels of lead, which is prohibited under federal law. EKSuccess Brands, a division of Wilton Brands Inc., at (855) 535-2099 or www.eksuccessbrands.com.

Animated Safari and Aquarium Lamps. Defective wiring in the lamps can cause an electrical short, posing fire and shock hazards to consumers. Nantucket Distributing Co. Inc., at (888) 287-3232 or www.christmastreeshops.com.

CONSUMER PRODUCTS (continued)

Beeni Baby Hats. A baby can spit up during use, posing an asphyxiation hazard. Kahn Enterprises LLC, at (612) 310-4053 or www.beeni.net.

Blade mCP X Bind-N Fly and Ready to Fly Remote Control Model Helicopters and Replacement Blade mCP X Main Blade Grips with Bearings. The main blade grips and main rotor blades can release from the main rotor head, posing an impact and laceration hazard. Horizon Hobby Inc., at (877) 504-0233 or www.bladehelis.com/MCPX.

B-Nimble Strollers. An audible click heard when the brake pedal is pressed can give a false impression that the brake is fully engaged when it is not. When the brake is not engaged, the stroller can move unexpectedly, posing a risk of injury to the child occupant. Britax Child Safety Inc., at (888) 427-4829 or www.britaxusa.com.

Calphalon Contemporary Cutlery Knife Sets. The tips of the 8-inch slicing knife and/or the 8-inch bread knife can protrude through the bottom slot row on the wooden block holder, posing a laceration hazard. Calphalon Corp., at (800) 809-7267 or www.calphalon.com.

Carrier Rack for Mounting Over Front Bicycle Wheel. The bicycle rack's mounting bracket can crack or break. When this happens, the rack can fall onto the bicycle's front wheel, posing a fall hazard to the rider. Quality Bicycle Products, at (877) 311-7686 or <http://civiacycles.com/aftermarketloringfrontrackrecall/>.

Children's Pain and Fever Concentrated Drops. This over-the-counter medicine contains acetaminophen, which calls for child-resistant packaging as required by the Poison Prevention Packaging Act. Although the original bottle has child-resistant packaging, a separate dropper unit provided for dispensing the drug to children does not. When in use, a child can access the medicine, posing serious health problems or death if more than the recommended dosage is consumed. Rugby Laboratories Inc., at (800) 645-2158.

Circo Aloma Infant Girls Sandals. The decorative plastic flowers can detach, posing a choking hazard. Target, at (800) 440-0680 or www.target.com.

Circo Child Booster Seats. The booster seat's restraint buckle can open unexpectedly, allowing a child to fall from the chair and be injured. Target, at (800) 440-0680 or www.target.com.

Emma's Garden Polka-Dot Girls' Dresses. The decorative buttons on the front of the dress can detach, posing a choking hazard. The TJX Companies Inc., at (800) 926-6299 or www.tjmaxx.com (U.S.) or (800) 646-9466 or www.winners.ca (Canada).

Full-Face Bicycle Helmets. The plastic buckle that connects the chin straps can fail, causing the helmet to come off the wearer's head. This poses a head injury hazard to riders in the event of a fall. Bell Sports, at (866) 892-6059 or www.bellsports.com.

GE Zoneline Air Conditioners and Heaters. An electrical component in the heating system can fail, posing a fire hazard to consumers. Sharp Corp., at (866) 918-8771 or www.geappliances.com/products/recall.

Glass Votive Candle Holders. The glass votive candle holders can shatter while in use, posing a fire and laceration hazard to consumers. Greenbrier International Inc., at (800) 876-8077 or www.dollartree.com.

GNC Women's Ultra Mega, Ultra Mega Active, Ultra Mega Energy and Metabolism, and GNC Prenatal Formula with Iron Multivitamins. The products contain iron but do not have child-resistant packaging, as required by federal law. If ingested by a child, these vitamins could cause serious injury or death. General Nutrition Corp., at (888) 462-2548 or www.gnc.com.

Golf Cars and Hospitality, Utility and Transport Vehicles. The brake pedal mounting blocks can crack and separate, resulting in a loss of braking ability. This can result in a crash. Club Car LLC, at (800) 227-0739 ext. 3580 or www.clubcar.com.

Gripper Shaker Musical Instrument. The handle can detach from the shaker, exposing a rough edge and posing a laceration hazard. The detached handle also exposes small steel pellets and a plastic plug, which pose choking hazards. Woodstock Percussion Inc., at (866) 543-2848 or www.woodstockpercussion.net.

Hamilton Beach Classic Chrome 2-Slice Toasters. The heating element in these toasters can remain energized indefinitely when an item is placed in the toaster, possibly igniting the contents and posing a fire hazard if the toaster is near flammable items. Hamilton Beach Brands Inc., at (800) 379-2200 or www.hamiltonbeach.com.

Husqvarna Yard Tractors with TuffTorq K46LD Transaxle. The yard tractor's transaxle can experience intermittent drive failure, posing a risk of reduced or lost braking ability. Husqvarna Professional Products Inc., at (877) 257-6921 or www.husqvarna.us.

Lithium-ion Batteries used in Hewlett-Packard and Compaq notebook computers. The recalled lithium-ion batteries can overheat and rupture, posing fire and burn hazards to consumers. Hewlett-Packard Company, at (888) 202-4320 or www.hp.com/support/BatteryReplacement.

CONSUMER PRODUCTS (continued)

Live Better One Daily Tablets and Live Better Complex Vitamin B50 Tablets. The iron supplements are not in child-resistant packaging, as required by the Poison Prevention Packaging Act. Ingesting multiple iron supplement tablets at once can cause serious injury or death to young children. International Vitamin Corp., at (866) 927-5470 or www.ivcinc.com.

Military Copters. The plastic blades of the helicopter can detach during operation, posing a laceration hazard. Excite USA, at (866) 791-4754 or www.Excite-Limited.com.

Portable Generator Battery. The hazard labels attached to the batteries used on the generators are printed in Japanese instead of English. As a result, consumers handling the battery may not be able to adequately avoid risks associated with the batteries. American Honda Motor Co., at (888) 888-3139 or www.hondapowerequipment.com/products/recalls.

Pourable NAPAFire and FIREGEL Gel Fuel Bottles and Jugs. The pourable gel fuel can ignite unexpectedly and splatter onto people and objects nearby when it is poured into a firepot that is still burning. This hazard can occur if the consumer does not see the flame or is not aware that the firepot is still ignited. Fuel gel that splatters and ignites can pose fire and burn risks to consumers. Napa Home and Garden, at (888) 893-2323 or www.napahomeandgarden.com/.

Quick Kids Junior Tennis Racquets. The orange grip tape on the tennis racket's handle contains high levels of lead. Lead is toxic if ingested by young children and can cause adverse health effects. GAMMA Sports, at (800) 333-0337 or www.gammasports.com.

Roman Shade Make-It-Yourself Kits. Strangulations can occur when a child places his/her neck between the exposed inner cord and the fabric on the back side of the shade or when a child pulls the cord out and wraps it around his/her neck. Wm. Wright Co., at (800) 545-5740 or www.simplicity.com.

Roman Shades. Strangulations can occur when a child places his/her neck between the exposed inner cord and the fabric on the back side of the blind or when a child pulls the cord out and wraps it around his/her neck. The Shade Store, at (800) 754-1455 or help@theshadestore.com.

Sage Creek Organics Children's Sleepwear. The garments fail to meet the federal flammability standards for children's sleepwear, posing a risk of burn injury to children. The garments are being recalled because they do not meet the tight-fitting sizing requirements. Sage Creek Organics, at (877) 513-2183.

Sewing Machine. The wires inside the sewing machine can short-circuit, posing a risk of fire. Janome America Inc., at (800) 631-0183 or www.elnausa.com.

TrimmerPlus Edger Attachments. The steel shaft that drives the edger blade can break during use, causing the edger blade to detach. If the blade detaches, it can hit the user or bystanders, posing a laceration hazard. MTD Products Inc., at (888) 848-6038 or www.mtdproducts.com.

Women's Dresses. The dresses fail to meet the federal flammability standard for wearing apparel, posing a fire hazard to consumers. Topson Downs, at (800) 241-2975 or customerservice@topsondowns.com.

Wooden Animal Drum. The paint used on the drum is in excess of the maximum allowable level of 90 ppm of lead, a violation of the federal lead paint standard. Cost Plus Inc., at (877) 967-5362 or www.worldmarket.com.

OUTRAGE, from page 12

Pennsylvania authorities but decided to take no action.

Largely because of the attention brought to this issue by Chris Barrish — who was awarded the national Al Nakkula Award for Police Reporting — the Delaware Legislature passed several measures to strengthen the state's medical practice act. As a result, its Board of Medical Practice has greatly increased the amount of discipline meted out to Delaware physicians during the past two years.

The new additions to the law include increased fines and the possibility of license revocation for medical officials who don't obey their legal duty to report suspected misconduct by a doctor, doctor disciplinary hearings that are open to the public and easier processes for emergency suspension. Also, doctors seeking to get or renew a license must disclose all previous investigations into their behavior —

The new additions to the [Delaware] law include increased fines and the possibility of license revocation for medical officials who don't obey their legal duty to report suspected misconduct by a doctor, doctor disciplinary hearings that are open to the public and easier processes for emergency suspension.

not just those resulting in punishment.

In the Public Citizen Health Research Group's annual ranking of serious disciplinary actions by state medical boards, Delaware had historically been one of the worst, ranking 50th in the country for three straight three-year periods ending in 2005.

But in the post-Bradley era of belated sensitivity to necessary improvement in protecting Delaware citizens from dangerous physicians, the board's rank rose to 13th in the country for the three-year period ending in 2010. So far, in 2011, there have been 14 serious disciplinary actions against Delaware physicians, including four for sexual

violations, one involving children.

Delaware now joins an increasing number of jurisdictions who have changed a long history of dangerously inadequate discipline of physicians. What they have in common is that almost entirely as a result of relentless reporting by the news media their newly awakened legislatures have started to pay more attention to this important issue. In the past decade, the boards in Arizona, the District of Columbia and North Carolina have greatly improved their protection of patients thanks to such reporting. ♦

Are your medicines SAFE?



Find out which drugs are safe — and which you should avoid — with Public Citizen's *WorstPills.org* and *Worst Pills, Best Pills News*.

To subscribe to *WorstPills.org*, our online database, for only \$15 a year, visit www.WorstPills.org and type in promotional code **PNJULY11** when prompted.

To subscribe to the monthly print edition of *Worst Pills, Best Pills News* for only \$10 a year, please mail a check payable to "Pills News" to 1600 20th St. NW, Washington, DC 20009.

www.WorstPills.org





Outrage of the Month! Hope for Delaware Emerges After Disaster for Its Children

On June 23, 2011, a Delaware judge found pediatrician Earl Bradley guilty on 24 counts of molesting dozens of his patients. Earlier investigations, revealed by Chris Barrish of *The (Del.) News Journal* in January 2010, reported that Bradley had “raped or molested more than 100 child patients and that complaints over a 15-year period about his inappropriate touching of girls never led to discipline or his arrest.”

During this time, government institutions, including law enforcement officials and the state’s Board of Medical Practice, as well as some physicians in Delaware, had been well aware of Bradley’s unconscionable behavior, but nothing had been done either to remove his license to practice medicine or to arrest him until well after additional, clearly preventable damage to children had occurred.

For example, in 1994, according to *The News Journal*, after being investigated in Philadelphia for allegedly touching a child improperly, Bradley moved his practice to the Delaware seashore town of Lewes and took a job at Beebe Medical Center.

Linda Ammons, dean of Widener Law in Delaware, investigated these events and found that:

- When a judge would not let state police search Bradley’s office

Delaware now joins an increasing number of jurisdictions who have changed a long history of dangerously inadequate discipline of physicians.

in December 2008, the judge told investigators he would sign a warrant for the pediatrician’s arrest, the report says. Prosecutors decided they didn’t have enough evidence to prove he was conducting inappropriate vaginal exams.

• During the yearlong period from the judge’s denial until Bradley’s arrest in December 2009, the pediatrician allegedly raped or sexually abused nearly 50 young girls, a review of indictments shows.

• Pennsylvania medical licensing authorities dismissed the original June 1994 complaint, and Philadelphia police decided the mother was “not credible,” Ammons wrote.

• Delaware’s Board of Medical Practice, which issued Bradley a license in April 1994, discussed the above-stated complaint with

see [OUTRAGE, page II](#)

NONPROFIT ORG
U.S. POSTAGE
PAID
FREDERICK, MD
PERMIT #999

Health Letter, Public Citizen Health Research Group
1600 20th Street, N.W., Washington, D.C. 20009



MOVING? SUBSCRIPTION? ADDRESS CORRECTION?
Please enter corrections or subscription information below. Return current mailing label. Mail to the address above.

NAME _____

ADDRESS _____

CITY, STATE, ZIP _____

SUBSCRIPTION

One year \$18 Two year \$30 Three year \$42

Enclose your check or money order made out to *Health Letter* CHAAA4

Printed on recycled paper.