Annual Adverse Drug Experience Report: 1996

October 30, 1997

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INTRODUCTION

This report presents a descriptive overview of the 159,504 evaluable[1], postmarket adverse drug experience (ADE) cases received by the US Food and Drug Administration (FDA) during calendar year 1996[2]. A case consists of the original report of an ADE on a patient plus any follow-up information.

At this time, October, 1997, the SRS has accumulated about 1.4 million cases. The primary purpose for maintaining the database is to serve as an early warning or signaling system for ADEs not detected during premarket testing. The ADE system depends upon

detection of an adverse clinical event by a health professional or consumer, attribution of the clinical event to prior administration of a particular drug ("suspect" drug), and reporting of the ADE to the manufacturer of the suspected drug or directly to FDA. Data from these ADE cases are coded and entered into the computerized ADE database. Copies of the ADE cases are stored on microfilm or an imaging system. Up to five drugs per case may be entered into the computerized ADE database; the five can be a combination of "suspect" and "concomitant" drugs. Up to four adverse events per case and their associated body systems can by coded into the database, using FDA's "Coding Symbols for Thesaurus of Adverse Reaction Terms" (COSTART).

Reporting of postmarket ADEs by health professionals and consumers is voluntary. They may send their reports directly to FDA ("Direct" reports), to the drug manufacturer ("Manufacturer" reports), or both. Drug manufacturers are required by law and regulation to submit to FDA postmarket ADE reports received by any means from health professional or consumers.

It is important to remember certain caveats when using data from FDA's postmarket ADE database:

1. For any given ADE case, there is no certainty that the suspected drug caused the ADE. This is because physicians and consumers are encouraged to report all suspected ADEs, not just those that are already known to be caused by the drug. The adverse event may have been related to an underlying disease for which the drug was given, to other concomitant drugs, or may have occurred by chance at the same time the suspect drug was administered.
2. Accumulated ADE cases may not be used to calculate incidences or estimates of drug risk. Numbers from these data should be carefully interpreted as reporting rates and not occurrence or incidence rates.

Over the next pages, various kinds of data and information are presented on the postmarket ADE cases computerized into the FDA ADE database during calendar year 1996. Due to rounding, the percentages in tables and graphs may not total to 100%. Figures 1 and 2 present copies of the postmarket ADE forms used by manufacturers and health professionals or consumers, respectively.

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[1] Excludes "React Uneval" unevaluable reactions cases.

[2] The 1996 postmarket ADE Computerized data file used for this report was created October 1997.

Standard MedWatch Form, front page

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For use by user-facilities, distributors and manufacturers for MANDATORY reporting

Page ____ of ____

PLEASE TYPE OR USE BLACK INK

A. Patient information

1. Patient identifier
In confidence

2. Age at time of event:
or
Date of birth:

3. Sex
☐ female
☐ male

4. Weight
_____ lbs
or
_____ kgs

B. Adverse event or product problem

1. ☐ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
☐ death _____
☐ life-threatening
☐ hospitalization – initial or prolonged
☐ disability
☐ congenital anomaly
☐ required intervention to prevent permanent impairment/damage
☐ other: _____

3. Date of event

4. Date of this report

5. Describe event or problem

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1
#2

2. Dose, frequency & route used
#1
#2

3. Therapy dates (if unknown, give duration)
#1
#2

4. Diagnosis for use (indication)
#1
#2

5. Event abated after use stopped or dose reduced
#1 ☐ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
#1
#2

7. Exp. date (if known)
#1
#2

8. Event reappeared after reintroduction
#1 ☐ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # – for product problems only (if known)
– –

10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device
☐ health professional
☐ lay user/patient
☐ other: _____

5. Expiration date

6.
model # _____
catalog # _____
serial # _____
lot # _____
other # _____

7. If implanted, give date

8. If explanted, give date

9. Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on _____

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Initial reporter

1. Name, address & phone #

phone #

2. Health professional?
☐ yes ☐ no

3. Occupation

4. Initial reporter also sent report to FDA
☐ yes ☐ no ☐ unk

FDA

FDA Form 3500A (1/96)

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

Standard MedWatch Form, back page

Medication and Device Experience Report

(continued)

Refer to guidelines for specific instructions

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

Page ____ of ____

F. For use by user facility/distributor–devices only

1. **Check one**
   - ☐ user facility
   - ☐ distributor

2. **UF/Dist report number**

3. **User facility or distributor name/address**

4. **Contact person**

5. **Phone Number**

6. **Date user facility or distributor became aware of event**

7. **Type of report**
   - ☐ initial
   - ☐ follow-up # ____

8. **Date of this report**

9. **Approximate age of device**

10. **Event problem codes** (refer to coding manual)
    - patient code
    - device code

11. **Report sent to FDA?**
    - ☐ yes
    - ☐ no

12. **Location where event occurred**
    - ☐ hospital
    - ☐ home
    - ☐ nursing home
    - ☐ outpatient treatment facility
    - ☐ outpatient diagnostic facility
    - ☐ ambulatory surgical facility
    - ☐ other:

13. **Report sent to manufacturer?**
    - ☐ yes
    - ☐ no

14. **Manufacturer name/address**

G. All manufacturers

1. **Contact office – name/address** (& mfring site for devices)

2. **Phone number**

3. **Report source** (check all that apply)
   - ☐ foreign
   - ☐ study
   - ☐ literature
   - ☐ consumer
   - ☐ health professional
   - ☐ user facility
   - ☐ company representative
   - ☐ distributor
   - ☐ other

4. **Date received by manufacturer**

5. (A)NDA # ____
   IND # ____
   PLA # ____
   pre-1938 ☐ yes
   OTC product ☐ yes

6. **If IND, protocol #**

7. **Type of report** (check all that apply)
   - ☐ 5-day ☐ 15-day
   - ☐ 10-day ☐ periodic
   - ☐ Initial ☐ follow-up # ____

8. **Adverse event term(s)**

9. **Mfr. report number**

H. Device manufacturers only

1. **Type of reportable event**
   - ☐ death
   - ☐ serious injury
   - ☐ malfunction (see guidelines)
   - ☐ other: ____

2. **If follow-up, what type?**
   - ☐ correction
   - ☐ additional information
   - ☐ response to FDA request
   - ☐ device evaluation

3. **Device evaluated by mfr?**
   - ☐ not returned to mfr.
   - ☐ yes ☐ evaluation summary attached
   - ☐ no (attach page to explain why not) or provide code: ____

4. **Device manufacture date**

5. **Labeled for single use?**
   - ☐ yes ☐ no

6. **Evaluation codes** (refer to coding manual)
   - method
   - results
   - conclusions

7. **If remedial action initiated, check type**
   - ☐ recall
   - ☐ repair
   - ☐ replace
   - ☐ relabeling
   - ☐ other:
   - ☐ notification
   - ☐ inspection
   - ☐ patient monitoring
   - ☐ modification/ adjustment

8. **Usage of device**
   - ☐ initial use of device
   - ☐ reuse
   - ☐ unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ **Additional manufacturer narrative** and/or 11. ☐ **Corrected data**

Please do NOT return this form to either of these addresses.

FDA Form 3500A - back

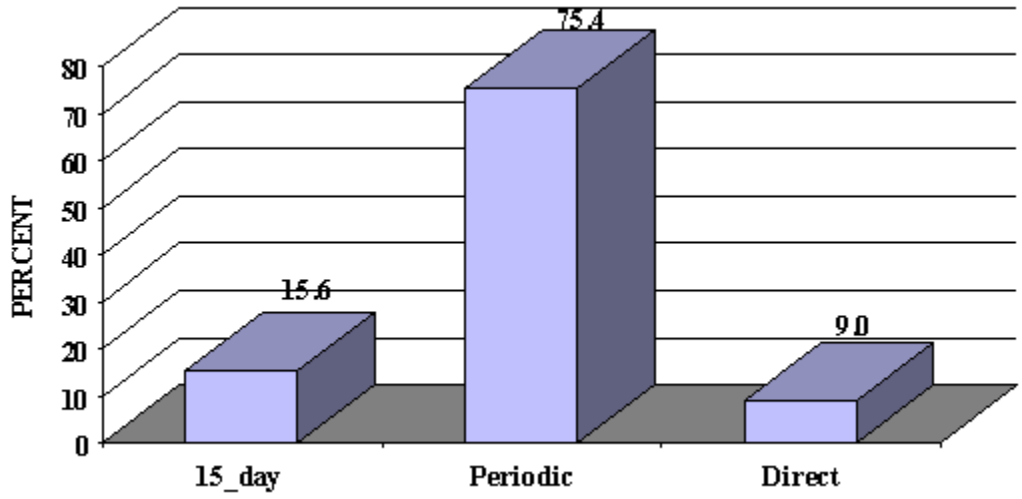
TYPES OF REPORTS

There are three types of reports in the FDA computerized postmarket ADE database:

1. Manufacturer-reported cases concerning ADEs not in present official FDA labeling with serious outcomes (i.e., death, life-threatening, hospitalization, permanent disability, congenital anomaly, cancer, or overdose). These cases are known in regulatory language as "**15-day Alert Reports**" because the manufacturer has 15 working days to submit this type of report to FDA.
2. All other manufacturer-reported cases. These cases are known in regulatory languages as "**Periodic Reports**" because the manufacturer is required to submit them to FDA on a cyclical basis.
3. Cases sent directly to FDA by health professionals or consumers ("**Direct Reports**").

As shown in Figure 3, reports submitted to FDA via manufacturers accounted for 91.0%(145,021) of the 159,504 postmarket ADE cases. Only 9.0%(14,483) were submitted directly to FDA. 15-day report were 15.6%(24,815) of the total.

Figure 3. Postmarket ADE Reports by Type of Report: 1996

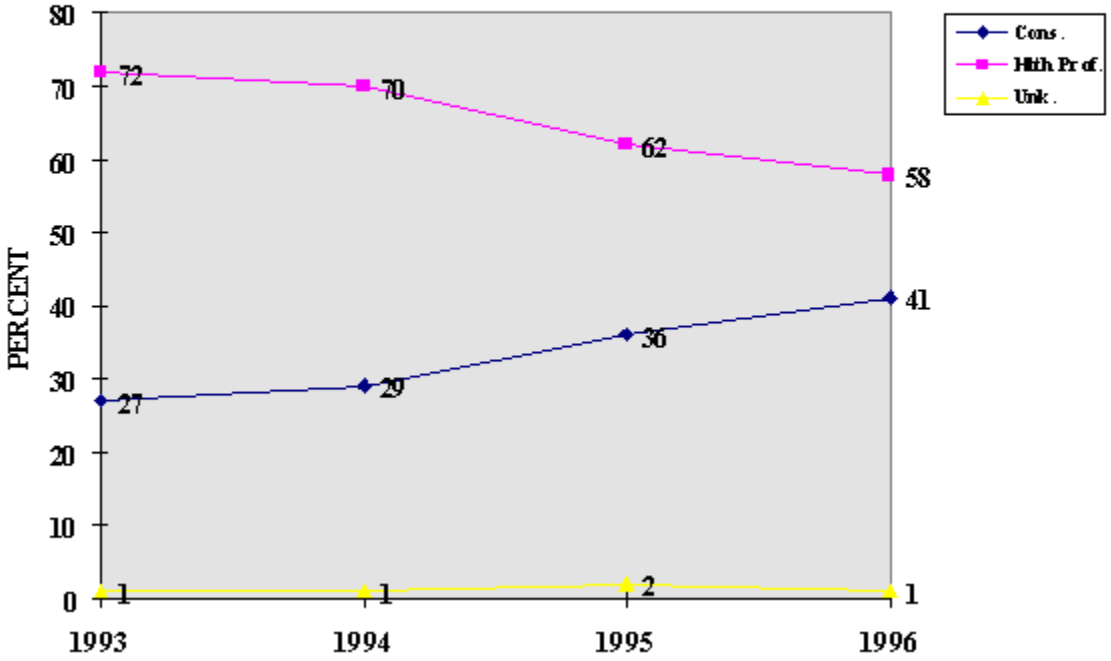


N = 159,504

REPORTING BY HEALTH PROFESSIONALS AND CONSUMERS

As shown in Figure 4, in 1996, there were 157,067 reporters for the 159,504 postmarket ADE cases, 64,752 (41.2%) reporters were consumers, 90,394 (57.6%) reporters were health professionals, and 1,921 (1.2%) were unknown sources. Figure 4 also shows that, over a four-year trend (1993-96), reports from consumers have increased both in absolute numbers and proportionally, whereas those from health professionals have gone up in absolute numbers.

Figure 4. ADE Reports By Health Professionals and Consumers, 1993-1996



Year: 1993 1994 1995 1996

N (000s)			N (000s)			N (000s)			N (000s)		
C	32		C	35		C	48		C	64	
H	86		H	84		H	81		H	90	
U	1		U	1		U	2		U	2	

GEOGRAPHIC LOCATION OF INITIAL REPORTER

As shown in Table 1, the initial reporter for 81.2% (129,521) of the 159,504 postmarket ADE cases was located within the US census regions; 9.6% (15,260) of cases were missing location.

There were 9.2% (14,723) of the postmarket ADE cases where the initial report source was foreign. There were four countries which each accounted for >= 9% of the foreign cases: France (31.2%), Japan (14.2%), United Kingdom (12.8%), Germany (9.2%).

Table 1. Postmarket ADE Reports by Geographic Location of Initial Reporter: 1996

	N	%
All Locations	***159,504***	***100***
US Census Region:	***129,521***	***81.2***
[a] **New England**	25,149	19.4
East South Central	23,355	18.0
Pacific	22,289	17.2
Middle West	22,207	17.2
West South Central	16,804	13.0
Middle Atlantic	16,763	12.9
Others	2,954	2.3
Foreign:	***14,723***	***9.2***
[b] **France**	4,593	31.2
Japan	2,094	14.2

United Kingdom	1,888	12.8
Germany	1,355	9.2
Others	4,793	32.6
Unknown	***15,260***	***9.6***

[a] US Census Regions are percentaged to 129,521
[b] Foreign countries are percentaged to 14,723

SEX AND AGE OF PATIENTS

As shown in Table 2, the ratio of female-to-male postmarket ADE cases was 1.7:1. For both females and males, the >= 60 year age group accounted for the greatest number of known sex-age cases.

Table 2. Postmarket ADE Reports by Reports by Sex & Age of Patient: 1996

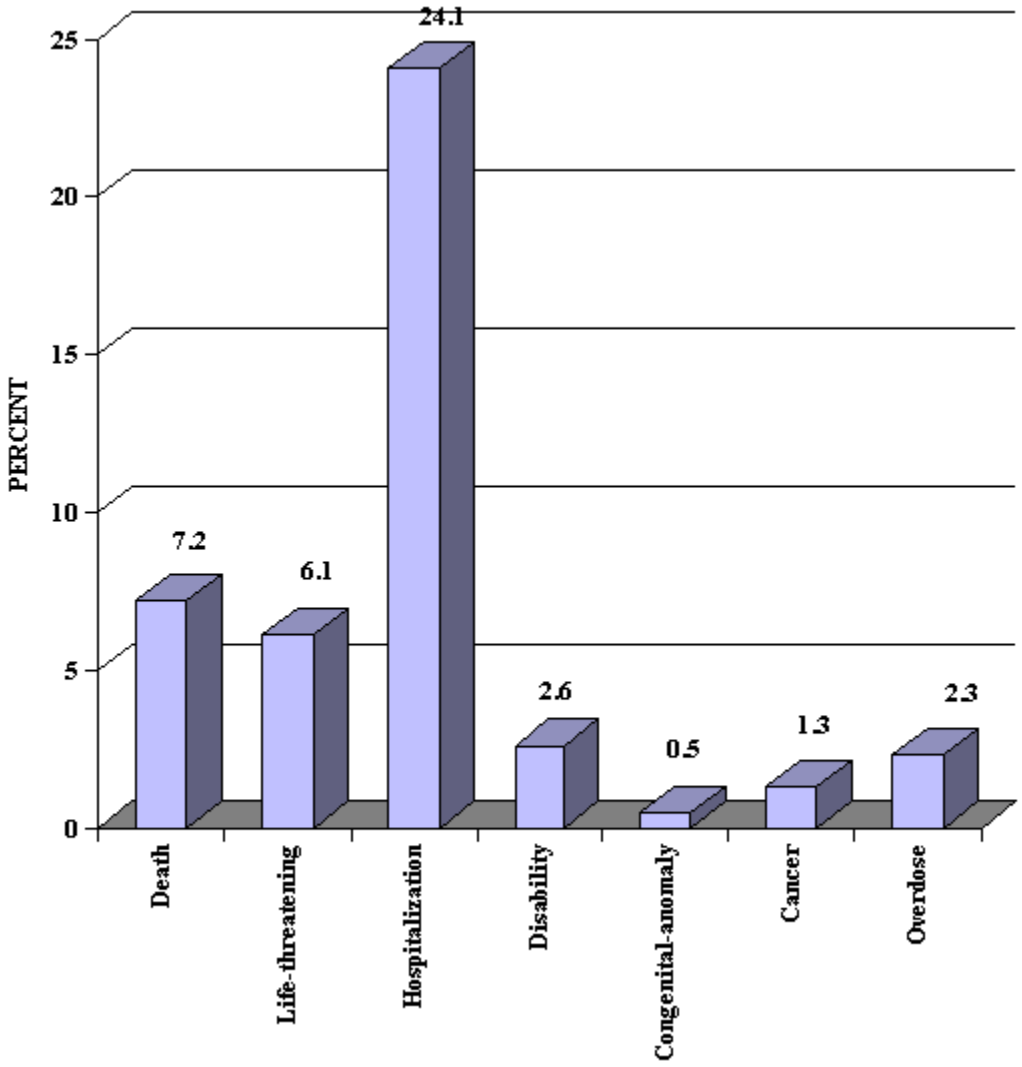
	N	**%**
ALL SEXES & AGES	***159,504***	***100***
All Females:	***91,200***	***57.2***
<= 19 yrs	5,971	3.7
20 - 39 yrs	19,855	12.4
40 - 59 yrs	20,980	13.2

>= 60 yrs	24,111	15.1
Unknown age	20,283	12.7
All Males:	***53,761***	***33.7***
<= 19 yrs	5,069	3.2
20 - 39 yrs	8,510	5.3
40 - 59 yrs	13,082	8.2
>= 60 yrs	17,418	10.9
Unknown age	9,682	6.1
Unknown Sex:	***14,543***	***9.1***
<= 19 yrs	439	0.3
20 - 39 yrs	163	0.1
40 - 59 yrs	242	0.2
>= 60 yrs	312	0.2
Unknown age	13,387	8.4

SERIOUS OUTCOMES

As shown in Figure 5, hospitalization was the most recorded serious outcome; congenital anomaly, the least. (One case could have more than one outcome).

Figure 5. Postmarket ADE Reports by Type of Serious Report: 1996



Serious Outcome

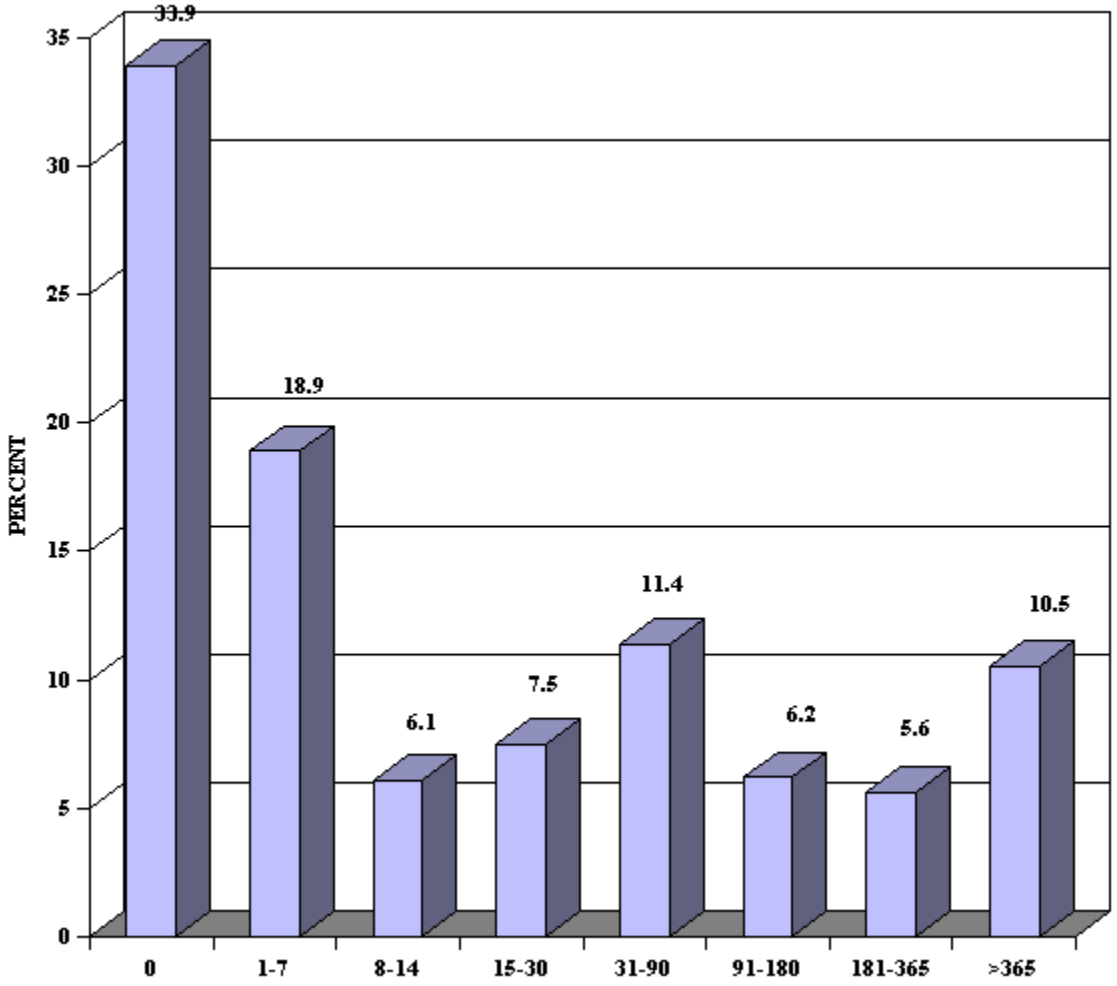
N = 105,599

LATENCY BETWEEN SUSPECT DRUG ADMINISTRATION AND ADE ONSET

As shown in Figure 6, of the 159,504 postmarket ADE cases, 53.6% (85,517) had both a drug start date and an adverse experience onset date for the first-listed suspect drug and first-listed adverse experience, respectively, and the drug date was computerized as

occurring before the adverse experience date. About half of these cases noted that the adverse event occurred within one week of drug initiation.

Figure 6. Postmarket ADE Reports by Latency Period: 1996



Latency (days)

N = 85,517

CLASSES OF SUSPECT DRUGS

Table 3 presents the top-10 ranked drug classes associated with the 174,905 suspect drugs computerized from the 159.504 postmarket ADE cases. The top-ranked drug class, central nervous system agents, accounted for approximately little less than one-quarter of

the drug class mentions[3]. Together with the second and third ranked drug classes, anti-infectives, and hormones and synthetic substitutes, these top three ranked drug classes comprised about half of the total drug class mentions.

Table 3. Postmarket ADE Reports by Top-10 Ranked Classes of Suspect Drugs: 1996

	N	%
All Suspect Drug Mentions	***174,905***	***100***
Central nervous system agents	39,541	22.6
Anti-infective agents	21,388	12.2
Hormones & synthetic substitutes	20,956	12.0
Cardiovascular drugs	18,076	10.3
Skin & mucous membrane agents	13,927	7.9
Antineoplastic agents	12,552	7.2
Gastrointestinal drugs	10,580	6.0
Unclassified therapeutic agents	10,397	5.9
Autonomic drugs	8,189	4.7
Blood formation and coagulation	3,707	2.1

[3] The drug classification used was the American Hospital Formulary Service Pharmacologic - Therapeutic Classification (American Society of Health-System Pharmacists, Bethesda, Maryland, 1997)

SUSPECT DRUGS BY ENTRY NAME AND NEW MOLECULAR ENTITY STATUS

Table 4 shows the top-10 ranked suspect drugs as entered on the 159,504 postmarket ADE reporting forms.

New Molecular Entities (NMEs) are defined as new drugs approved within the past three years. For this 1996 report, NMEs are new drugs approved during 1993-96. Of the 174,905 suspect drugs computerized from the 159,504 postmarket ADE cases, 30.2%(29,584) involved NMEs.

Table 4. Postmarket ADE Reports by Top-10 Ranked Suspect Drugs: 1996

	N	%
All Suspect Drug Mentions	***174,905***	***100***
Fosamax™	6,197	3.5
Norplant™	5,957	3.4
Prozac™	3,506	2.0
Pepcid AC™	3,104	1.8
Estraderm™	2,890	1.7
Femstat™	2,648	1.5
Rogaine™	2,435	1.4
Paragard™ T380A	2,172	1.2
Nix™	2,077	1.2
Zoloft™	2,070	1.2

™ - Trademark

DRUG CLASSES STRATIFIED BY HEALTH PROFESSIONALS OR CONSUMERS, TYPE OF REPORT, AND YEAR

Table 5 shows the top-five ranked drug classes[3] associated with suspect drugs, stratified by whether the initial reporter was a health professional or consumer, the type of report, and year the cases was computerized into the FDA postmarket ADE database.

1996 Data. In 1996, there were 155,529 drug class mentions where type of initial reporter and type of report were known. For consumers, only two of the top-five ranked drug classes were common to all report types: central nervous system agents and hormones and synthetic substitutes. For health professionals, there were four drug classes of the top-five ranked drug classes common to all report types: central nervous system agents, antineoplastic agents, anti-infective agents, and cardiovascular drugs. The only drug class in the top-five ranked drug classes common to both consumers and health professionals across report types was central nervous system agents.

Table 5. Top-5 Ranked Drug Classes Per Type of Reporter & Report: 1996

Reporter Type	Report Type	Drug Class	N	%
ALL	***ALL***	***ALL***	***155,529***	***100***
Consumer	***All***	***All***	***64,858***	***41.7***
	Mfr 15-day	***All***	***2,820***	***1.8***
		Central nervous system agents	689	0.4
		Hormones and synthetic substitutes	482	0.3
		Anti-infective agents	309	0.2
		Cardiovascular drugs	271	0.2
		Autonomic drugs	233	0.1

	Mfr Periodic	***All***	***61,225***	***39.4***
		Hormones and synthetic substitutes	11,709	7.5
		Skin and mucous membrane agents	10,612	6.8
		Central nervous system agents	10,073	6.5
		Gastrointestinal drugs	7,080	4.6
		Cardiovascular drugs	5,504	3.5
	Direct	***All***	***813***	***0.5***
		Central nervous system agents	222	0.1
		Skin and mucous membrane agents	132	0.1
		Autonomic drugs	88	0.1
		Anti-infective agents	87	0.1
		Cardiovascular drugs	43	0.0
Health Professional	***All***	***All***	***90,671***	***58.3***
	Mfr 15-day	***All***	***20,200***	***13.0***
		Central nervous system agents	4,264	2.7
		Anti-infective agents	3,851	2.5
		Antineoplastic agents	3,165	2.0
		Cardiovascular drugs	2,582	1.7
		Hormones and synthetic substitutes	1,274	0.8
	Mfr Periodic	***All***	***56,998***	***36.6***

		Central nervous system agents	15,324	9.9
		Anti-infective agents	8,061	5.2
		Cardiovascular drugs	5,953	3.8
		Hormones and synthetic substitutes	5,434	3.5
		Antineoplastic agents	3,962	2.5
	Direct	***All***	***13,473***	***8.7***
		Central nervous system agents	3,713	2.4
		Anti-infective agents	2,477	1.6
		Cardiovascular drugs	1,736	1.1
		Antieoplastic agents	1,398	0.9
		Blood formation and coagulation	919	0.6

ROUTES OF SUSPECT DRUGS

Table 6 presents the top-10 ranked routes of administration associated with the suspect drugs. There were 156,759 routes mentioned in conjunction with the 159,504 postmarket ADE cases. About three-fifths of the route mentions noted the oral route of administration.

Table 6. Postmarket ADE Reports by Top-10 Ranked Routes of Administration of Suspect Drugs: 1996

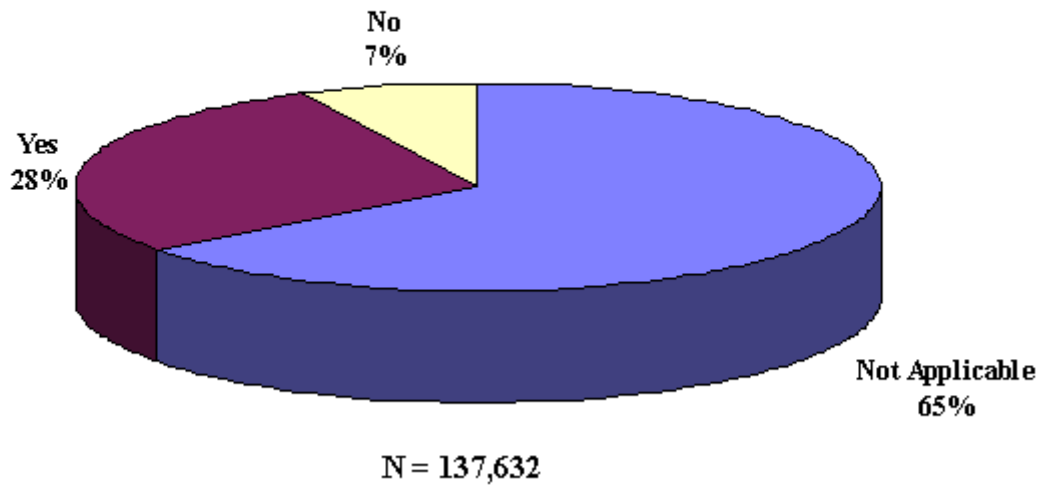
	N	**%**
All Routes	***156,759***	***100***

Oral	99,421	63.4
Intravenous	14,873	9.5
Subcutaneous	8,204	5.2
Topical	8,181	5.2
Transdermal	7,460	4.8
Vaginal	3,798	2.4
Inhalation	2,739	1.7
Intrauterine	2,318	1.5
Ophthalmic	2,094	1.3
Intramuscular	2,029	1.3

ABATEMENT OF ADVERSE EVENT

For the 174,905 suspect drug mentions, 78.7% (137,632) had an answer to the question of whether the adverse event abated after the suspect drug was stopped or the dose was reduced. Figure 7 shows the distribution of responses. About one-quarter of these 137,632 abate mentions indicated a positive dechallenge ("Yes" response).

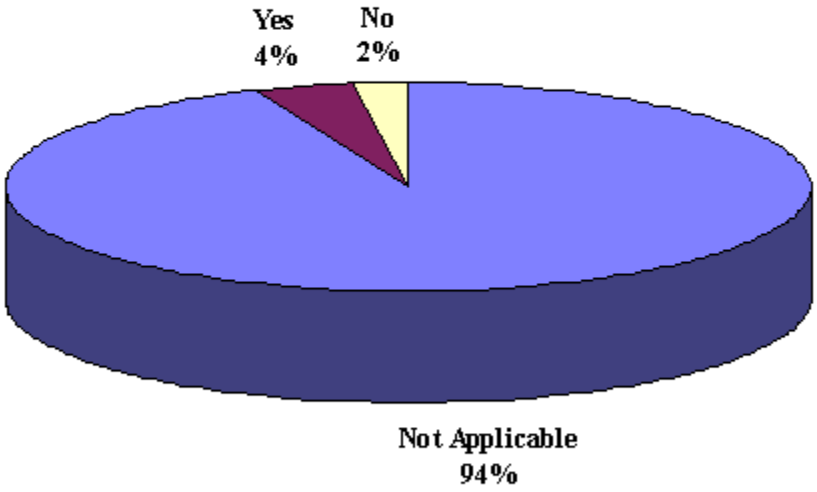
Figure 7. Postmarket ADE Reports by Abate response: 1996



REOCCURRENCE OF ADVERSE EVENT

For the 174,905 suspect drug mentions, 76.2% (132,296) had an answer to the question of whether the adverse event reappeared after reintroduction of the suspect drug. Figure 8 shows the distribution of responses. Four percent (5,309) of these 132,296 reoccur mentions indicated a positive rechallenge ("Yes" response).

Figure 8. Postmarket ADE Reports by Reintroduction Response: 1996

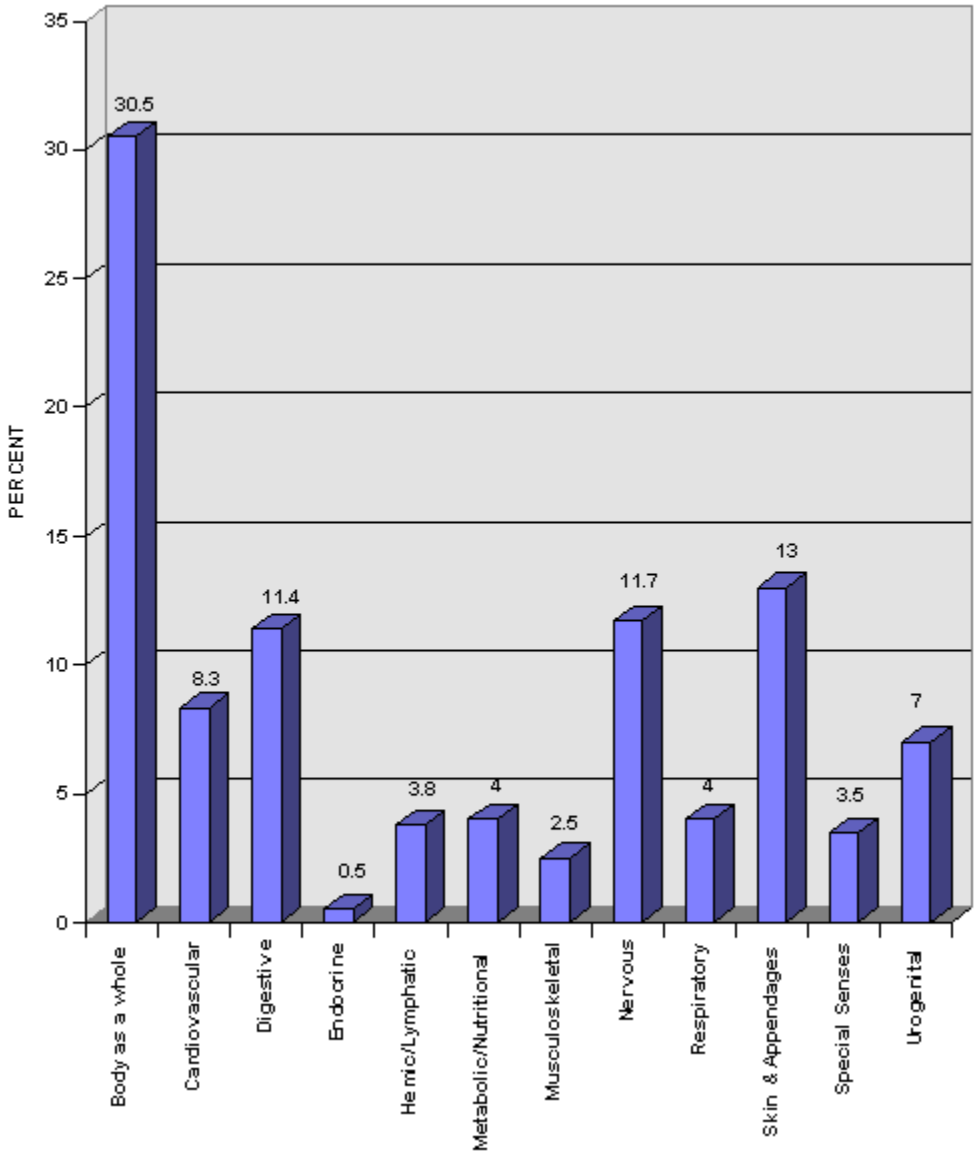


N = 132,296

BODY SYSTEMS

There were 159,515 body system mentions associated with the adverse events of the 159,504 postmarket ADE cases. The distribution of these mentions across the 12 body system mentions is presented in Figure 9. Four body systems each had > 10% of the 159,515 body system mentions: body as a whole (systemic adverse events) - 30.5%, skin and appendages system - 13%, nervous system - 11.7%, and digestive system - 11.4%.

Figure 9. Postmarket ADE Reports by Body System: 1996



N = 159,515

ADVERSE EVENTS

Table 7 shows the top-10 ranked adverse events reported with the 159,504 postmarket ADE cases. The top ranked ADE was " No drug effect: - 10% of the ADE cases reported this event.

Table 7. Top-10 Ranked Adverse Events: 1996

Adverse Event	N	%
All Postmarket ADE Reports	***159,504***	***100***
No drug effect	15,918	10.0
Headache	5,133	3.2
Rash	4,090	2.6
Application site reaction	3,583	2.2
Diarrhea	2,445	1.5
Urticaria	2,373	1.4
Alopecia	2,237	1.4
Aggravation of existing reaction	2,236	1.4
Dizziness	2,002	1.3
Abdominal pain	1,875	1.2

DRUG CLASSES ASSOCIATED WITH BODY SYSTEM ADVERSE EVENTS

Table 8 presents the four body systems comprising the most adverse events, each of which has been crosstabulated by its top-five ranked suspect associated drug classes[3]. Three drug classes were in the top-five ranks for all four body systems, central nervous system agents, cardiovascular drugs, and anti-infective agents.

Table 8. Top-4 Ranked Body Systems with Their Respective Top-5 Ranked Suspect Drug Classes: 1996

Body System	Suspect Drug Class	N	%
Body as a whole	***All***	***53,050***	***100***
	Central nervous system agents	12,131	22.9
	Hormones and synthetic substitutes	7,216	13.6
	Skin and mucous membrane agents	6,378	12.0
	Anti-infective agents	4,816	9.1
	Cardiovascular drugs	4,566	8.6
Skin and Appendages	***All***	***21,792***	***100***
	Hormones and synthetic substitutes	3,948	18.1
	Skin and mucous membrane agents	3,689	16.9
	Anti-infective agents	3,178	14.6
	Central nervous system agents	2,941	13.5
	Cardiovascular drugs	1,931	8.9
Nervous System	***All***	***20,515***	***100***
	Central nervous system agents	8,265	40.3
	Anti-infective agents	2,209	10.8
	Cardiovascular drugs	1,763	8.6
	Hormones and synthetic substitutes	1,463	7.1
	Autonomic drugs	1,425	7.0
Digestive System	***All***	***20,059***	***100***

	Central nervous system agents	4,105	20.5
	Anti-infective agents	4,081	20.3
	Gastrointestinal drugs	2,355	11.7
	Unclassified therapeutic agents	2,256	11.2
	Cardiovascular drugs	1,900	9.5

ANNUAL FOI REPORT

1996

In 1996, the Surveillance and Data Processing Branch (SDPB) received a total of 2,162 Freedom of Information (FOI) requests. These requests were for adverse reaction cases collected by the Food and Drug Administration's Spontaneous Reporting System (SRS). All requests are logged in by the central FOI office and triaged to various responsive divisions throughout the Center for Drugs.

SDPB processed FOI requests utilizing several forms of data accession. Compressed ASCII files were provided to mostly third-party businesses. Microfiche line listings or paper copies were also available depending on the preference of the requester. Case reports from the SRS database were obtained by people wanting a formalized version of the Medwatch form.

Law firms comprised the most FOI requests, with third-party organizations ranking second. Third were the pharmaceutical companies and last were consumers. However, consumers made more inquiries in 1996 than in previous years. This could have been attributed to media reporting and those consumers wanting to establish a more significant role in their drug therapy.

Hal Stepper