U.S. v Caronia: Misdemeanor or Constitutional Right?
BY: TAMARA YUNUSOVA, STAFF EDITOR

On December 3, 2012, the U.S. Second Circuit Court of Appeals became the first court in the nation to authorize off-label drug promotion under the First Amendment. The heavily-disputed ruling, which is headed for further appeal, will have far-reaching implications for pharmaceutical companies and drug regulation policy. In a 2-1 decision, the Court of Appeals revoked the conviction of a sales representative who sold drugs for conditions not approved by the Food and Drug Administration (FDA).

Alfred Caronia, a sales representative of Orphan Medical (later acquired by Jazz Pharmaceuticals), was promoting the prescription drug sodium oxybate (Xyrem®). Listed as a Schedule III drug under the Controlled Substances Act, Xyrem® is a central nervous system depressant which won FDA approval in 2002 to treat cataplexy and narcolepsy.2 Caronia personally promoted Xyrem® for insomnia, fibromyalgia, Parkinson’s disease, chronic pain, general muscle disorders and other off-label uses to prescribers.6 As a target of federal investigation in 2005, he was secretly recorded discussing the unapproved uses of the drug with a prescriber.1 He was convicted in 2008 for introducing a misbranded drug into interstate commerce, a violation of the Food, Drug, and Cosmetic Act.1

Contending that proscribing the provision of truthful and non-misleading information to prescribers for off-label use infringed upon his right to free speech, Mr. Caronia appealed to the higher courts. The violation of a constitutionally protected right was echoed by the Second Circuit’s ruling which stated that “the government cannot prosecute pharmaceutical manufacturers and their representatives under the Food, Drug, and Cosmetic Act for speech promoting the lawful off-label use of an FDA approved drug.”5

“In the fields of medicine and public health, where information can save lives, it only furthers the public interest to ensure that decisions about the use...
of prescription drugs, including off-label usage, are intelligent and well-informed,” wrote Circuit Judge Denny Chin.4

While pharmaceutical representatives are barred from promoting drugs off-label, physicians are free to prescribe drugs for off-label conditions. In that light, prohibiting sales representatives to promote drugs off label demands further scrutiny. Barring sales representatives from imparting truthful information about off-label uses when such uses are not illegal to begin with, essentially, prosecutes sales representatives for their speech, a violation of their First-Amendment rights.

About off-label prescribing rights, the Second Circuit ruling stated “prohibiting off-label promotion by a pharmaceutical manufacturer while simultaneously allowing off-label use ‘paternalistically’ interferes with the ability of physicians and patients to receive potentially relevant treatment information; such barriers to information about off-label use could inhibit, to the public’s detriment, informed and intelligent treatment decisions.”6

Whereas granting off-labeling rights leads to informed and intelligent decisions, opponents argue that legalizing off-label drug promotion will undermine the FDA’s role in drug regulation. “The majority calls into question the very foundations of our century-old system of drug regulation,” states dissenting Judge Debra Ann Livingston. “If drug companies were allowed to promote F.D.A. - approved drugs for unapproved uses, they would have little incentive to seek FDA approval for those uses.”5

The Caronia case is not the first of its kind to trigger the First Amendment reflex. In Sorrell vs. IMS Health, the U.S. Supreme Court repealed a Vermont law that forbade pharmaceutical companies to purchase prescribing information for marketing purposes, a practice known as data mining.1 Ruling that data mining is protected under the first amendment, the Supreme Court voided the Vermont law that sought to prohibit this action.

With a verdict that staggers between a misdemeanor and a constitutional right, the Alfred vs. Caronia case poses some serious legal questions about where the boundaries of the First Amendment lie. Previously, off-labeling cases were settled as soon as it was proven that the drug was misbranded or promoted for unapproved purposes. Now, however, with the authorization of off-label promotion, litigation must go further to prove that the efforts to promote the drug were untruthful and misleading.

“It’s very significant because it’s going to make F.D.A., in its promotion cases focus on the kinds of speech that are more likely to harm consumers, such as false or misleading marketing versus something that is not approved” said Gerald Masoudi, former chief counsel of the FDA. 5

In addition to its accompanying changes in litigation, the Caronia case promises dynamic changes in traditional business policy. Prior to U.S. vs. Caronia, to avert the misbranding charge, pharmaceutical companies would invest millions of dollars annually on training programs.3 For instance, in July 2012, GlaxoSmithKline agreed to pay $3 million in fines for off-label promotion of antidepressants.6 Aside from the great investments devoted to compliance programs, companies would spend hefty sums to settle allegations of off-label promotion. For its marketing of Risperidone (Risperdal) in August 2012, Johnson & Johnson pharmaceutical unit reached a $181 million consumer fraud settlement with 36 states and the District of Columbia.6 Under the formidable Park doctrine, the government could prosecute individual executives for off-label speech made by members in the company irrespective of the executive’s direct involvement or knowledge about the conduct.3 With the legalization of off-label promotion, pharmaceutical companies will no longer face such penalties.

The Caronia case raises prominent questions about drug promotion, regulation, and policy. If approved, off-label promotion will broaden the knowledge of both patients and physicians of various drug therapies, a hallmark of intelligent decisions.

**SOURCES:**


QUOTE OF THE MONTH
BY: ALEENA CHERIAN, CO-COPY EDITOR

someone else is happy with less than what you have.

-ANONYMOUS-

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CROSSWORD PUZZLE
BY: MAHDIEH DANESH YAZDI, ASSOCIATE STUDENT EDITOR

Across
2. Inactivated polio vaccine which protects against poliovirus types 1
5. Rotavirus vaccine given to infants in a three-dose series at 2
8. Meningococcal vaccine licensed for use in patients 9 months-55 years of age
9. Vaccine that immunizes against human papillomavirus types 6
12. Hepatitis B vaccine produced by Merck
18. DTap; often confused with Adacel
19. Hepatitis A + Hepatitis B recombinant vaccine
20. Hepatitis B vaccine produced by GlaxoSmithKline
21. Haemophilus b conjugate vaccine approved only as a booster dose

View Answers on Page 11

Down
1. One of three vaccines pharmacists can administer in New York in patients older than 60
3. Pneumococcal conjugate vaccine available as 7-valent or 13-valent
4. Only formulation of influenza vaccine with live antigen
5. Pneumococcal conjugate vaccine available as 23-valent
6. Tdap; licensed for use in patients 10 years of age or older
7. Patients born before 1957 may not have to receive this vaccine
10. Vaccine that immunizes against human papillomavirus types 16
11. Meningococcal polysaccharide vaccine preferred in patients 56 years of age or older
14. Vaccine that protects against varicella
15. Hepatitis A vaccine administered as a dose of 1440 ELISA units with a booster dose of 1440 ELISA units 6-12 months later
16. Only influenza vaccine available as an intradermal injection
17. Rotavirus vaccine given to infants in a two-dose series at 2 and 4 months of age
The following medications are easily confused. Try to match each one with its corresponding fun fact.

If you need help, please view the answers on page 23.

1. This anticonvulsant is indicated for generalized seizures of Lennox-Gastaut syndrome, generalized tonic-clonic seizures, partial seizures, and bipolar disorder. Sudden discontinuation of the drug may induce seizures. Adverse effects include Stevens-Johnson syndrome, aseptic meningitis, neutropenia, thrombocytopenia, and worsening depression.
   - A. Lamictal®
   - B. Lamisil®
   - C. Lamivudine
   - D. Lamotrigine
   - E. Levetiracetam
   - F. Levemir®
   - G. Levocarnitine
   - H. Levocetirizine
   - I. Levothyroxine
   - J. Liothyronine
   - K. Lovenox®

2. This is the brand name of the medication described above.

3. This anticonvulsant is indicated for myoclonic seizures, generalized tonic-clonic seizures, and partial seizures. Sudden discontinuation of the drug may induce seizures. Adverse effects include Stevens-Johnson syndrome and depression. This medication is available in both oral tablet and solution dosage forms.

4. This thyroid supplement is a synthetic form of natural T3. Though more potent than T4, due to its short half-life, it must be dosed multiple times a day.

5. This thyroid supplement is a synthetic form of natural T4. With a half-life roughly seven times that of T3, it is dosed only once daily. There are numerous brand and generic formulations of this hormone that are AB rated, but the American Association of Clinical Endocrinologists (AACE) recommends that patients remain on one formulation to ensure consistent thyroid hormone levels.

6. This nucleoside reverse transcriptase inhibitor is indicated for both HIV infection and chronic viral hepatitis. This drug may cause pancreatitis, lactic acidosis, lipodystrophy, decreased appetite, headache, or fatigue.

7. This supplement is indicated for carnitine deficiency. It is available in an intravenous formulation administered to those with acute metabolic crisis or end stage renal disease following hemodialysis and in an oral solution formulation which is administered following meals two to three times daily.

8. This antihistamine is indicated for seasonal and perennial allergic rhinitis and idiopathic urticaria. Oral tablets should be taken once daily with or without food in the evening. Children can be dosed with either the oral solution or by splitting tablets in half.

9. This antifungal agent is indicated for onychomycosis, dermal mycosis, and tinea capitis. Dosing is 250 mg once daily for six weeks for fingernails or twelve weeks for toenails, and symptomatic improvement of the nailbeds may take several months.

10. This injectable is a low molecular weight heparin anticoagulant. It is indicated for deep vein thrombosis prophylaxis for postoperative knee and hip replacements and abdominal surgery and in patients with acute restricted mobility; and for acute ST-segment elevation myocardial infarction (STEMI). It is available in prefilled syringes which are administered subcutaneously at alternating injection sites.

11. This injectable is insulin detemir. It is indicated for diabetes mellitus types 1 and 2. This subcutaneous injection should be administered in the thigh, abdominal wall, or upper arm, and injection sites should be rotated. This long-acting insulin should not be mixed with other insulins in the same syringe.

MATCHING CHALLENGE: LOOK-ALIKES, SOUND-ALIKES

BY: ADDOLORATA CICCONE, CO-COPY EDITOR
St. John’s University
College of Pharmacy and Health Sciences

PharmD
Class of 2013

Graduation Committee Meeting

For information about upcoming meetings, times, and location:

Contact: Lunbao [Jerry] Huang
Lunbau.huang07@stjohns.edu
On January 18, 2013, the U.S. Food and Drug Administration (FDA) announced a new approval for Botox, generically known as OnabotulinumtoxinA. Patients diagnosed with urinary incontinence due to an overactive bladder can be prescribed Botox, if they are unable to take or are unresponsive to anticholinergic medications. This new indication is supported by two clinical trials of 1,105 patients with symptoms of overactive bladder, where patients randomly received injections of 100 units of Botox or placebo. After 12 weeks, those treated with Botox experienced urinary incontinence an average of 1.6 to 1.9 times less per day and also needed to urinate on average 1.0 to 1.7 times less per day than the placebo group.1

Currently, anticholinergics are the standard drug class used to treat overactive bladder and urge urinary incontinence. Urinary incontinence (UI) can be classified based on etiology into urge urinary incontinence (UUI), stress urinary incontinence (SUI), mixed UI, overflow UI, and functional UI.2 UUI is due to over stimulation of the bladder, resulting in increased urinary frequency and urgency. Possible symptoms of urinary incontinence related to bladder overactivity are increased urinary frequency (>8 micturitions per day), urgency with or without urge incontinence, nocturia (>1 micturition per night) and enuresis.3 Inhibition of M3 receptors in the bladder is the primary target of the antimuscarinic agents oxybutynin, tolterodine, solifenacin, darifenacin, and trospium.2 However, with these drugs is the typical adverse effect profile of antimuscarinics, such as dry mouth, constipation, confusion, and visual impairment. Oxybutynin remains the drug of choice and the gold standard against which other drugs are compared.3

A clinical trial published in October 2012 in the New England Journal of Medicine compared anticholinergic therapy to OnabotulinumtoxinA to treat urgency urinary incontinence. The study included only women and looked for reductions in episodes of UUI over 6 months, improved quality of life, and side effects.4 Participants were randomized into two groups. One group was given oral solifenacin at a starting dose of 5 mg daily with an initial option of dose escalation followed by an option to switch to trospium XR, in addition to a placebo single injection. In the second group, participants were given a single injection of 100 U of OnabotulinumtoxinA along with an oral placebo regimen. The authors found no significant difference between anticholinergic drugs and OnabotulinumtoxinA in reducing the frequency of episodes of urgency incontinence or improving quality of life. What distinguished each therapy was the regimen, the route of administration, and the adverse effect profile. Anticholinergic medications resulted in more occurrences of dry mouth whereas OnabotulinumtoxinA resulted in higher risks of intermittent catheterization and urinary tract infections.4

For overactive bladder, the recommended dose is 100 Units of Botox, which is also the maximum recommended dose. Prophylactic treatment for urinary tract infection is also important. Antibiotics, other than aminoglycosides, should be administered 1 – 3 days pre-treatment, on the day of treatment, and 1 – 3 days post-treatment to reduce this risk.5

In conclusion, prescribers and pharmacists now have an alternative they can offer or recommend to patients who are unresponsive to anticholinergic therapy, intolerant of anticholinergic side effects, or have difficulty adhering to a daily regimen. Adherence may become a problem for those taking daily anticholinergics. Of course, prescribers should also consider the cost of both treatment options when choosing what is optimal for the patient.

SOURCES:
Perampanel (Fycompa®) has received the U.S. Food and Drug Administration (FDA) approval for the adjunctive treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy aged 12 years and older. The drug, manufactured by Eisai Inc., is already approved for use in Iceland, Norway, and the European Commission.

Epilepsy, sometimes referred to as seizure disorder, is defined by the occurrence of at least two unprovoked seizures separated by 24 hours. A seizure is a temporary disturbance in brain function in which groups of nerve cells in the brain signal abnormally and excessively. Partial seizures, the most common type of seizure seen in people with epilepsy, affect only a limited or localized area of the brain; however they can quickly spread to other parts of the brain.

According to the Centers of Disease Control and Prevention (CDC), about two million people in the United States have epilepsy and more than one-third of people with epilepsy experience seizures despite taking current available treatments. Perampanel is the first and only licensed anti-epileptic drug (AED) to selectively target AMPA receptors, a receptor in the brain which plays a critical role in the spread of epileptic seizures. This drug reduces neuronal hyperexcitation associated with seizures by targeting glutamate activity at postsynaptic AMPA receptors.

The approval of perampanel was primarily based on three Phase III studies (304, 305, and 306). All three studies – which were multi-center, randomized, double-blind, placebo-controlled, dose-escalation, and parallel group studies – evaluated the efficacy and safety of perampanel compared to a placebo given as adjunctive therapy in patients age 12 years and older with partial-onset seizures. In the first study, the percentage of patients who experienced a decrease in seizure frequency of at least 50% was 37.6% for patients taking 8 mg perampanel and 36.1% for patients taking 12 mg perampanel, compared with 26.4% of patients taking placebo. In the second study, 33.3% and 33.9% of patients taking 8 mg and 12 mg perampanel respectively showed a decrease in seizure frequency of at least 50%, compared with 14.7% of patients taking placebo. The third study showed a significant decrease in seizure frequency only in patients taking 4 mg and 8 mg perampanel, but not in patients taking a dose of 2 mg. These studies demonstrated that perampanel significantly reduced seizure frequency in patients with partial-onset seizures with or without secondarily generalized seizures.

Fycompa® must be titrated in order to optimize the balance between efficacy and tolerability. It should be used with caution in elderly, taking into account the drug interaction potential in polymedicated patients. Dose adjustment is not re-
quired in patients with mild renal impairment; how-
ever, dose increases in patients with mild and mod-
erate hepatic impairment should be based on clini-
cal response and tolerability.4

Perampanel has the benefit of convenient, once-
daily dosing at bedtime and is the only third gener-
ation partial epilepsy treatment approved to treat ad
dolescents with epilepsy from launch.4 Despite the 
various benefits, the drug does come with a host of 
potential side effects. A boxed warning flags the 
risks of life-threatening neuropsychiatric side effects 
including mood changes and other mental disturb-
ances, including aggression, anxiety, and paranoia.4

More common side effects include dizziness and 
weight gain.

The FDA has recommended that perampanel be 
classified by the U.S. Drug Enforcement Administra-
tion (DEA) as a scheduled drug.1 The DEA will re-
view the FDA’s recommendation and determine the 
final scheduling designation. Once the DEA has pro-
vided the final scheduling designation, Eisai will an-
nounce when perampanel (Fycompa®) will be avail-
able to patients and physicians in the United States.

SOURCES:
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   domized global phase III study 305. Epilepsia 
   2012
   Randomized phase III study 306: Adjunctive 
   perampanel for refractory partial-onset sei-

MATCHING CHALLENGE: LOOK-ALIKES, SOUND-ALIKES (ANSWERS)

BY: ADDOLORATA CICCONE, CO-COPY EDITOR

Go back to Page 10?

1 = D, 2 = A, 3 = F, 4 = J, 5 = I, 6 = C, 7 = G, 8 = H, 9 = B, 10 = K, 11 = E

SOURCES:
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3. Roberts DT, Taylor WD, and Boyle J. Guidelines for the treatment of onychomycosis. British Journal of 
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We will feature your work in our next issue!
Dear Reader,

We are always looking to engage with each of you. If you are a talented cartoonist or have a passion for art, feel free to contact one of the editors. It is a great way to express yourself and earn a spotlight for your artistic skills while drawing attention to an aspect of the pharmacy profession.

Can't draw? No problem, take pictures instead! We need photographers who can attend campus events and seminars that are related to healthcare or the pharmacy profession. Please feel free to send us the pictures with one or two paragraphs explaining the event. Perhaps you have a passion for writing; if so, feel free to write to us in response to an article you read. Even if it is just a question or a few comments on an article, email us!

Don't like what you see in the newsletter? Then let us know! Tell us what you would like to see in the newsletter, what topics you are interested in, and/or if you wish to read more about a specific topic. The newsletter is for you; so, your feedback is very important to us.

Do you have some clinical knowledge or experiences to share? Feel free to send us interesting drug information questions you have answered or share what you have learned throughout your rotations.

This is a commitment-free way to stay involved with the pharmacy profession. Contributing to our newsletter does not obligate you to contribute to every issue. We are more than happy to have guest authors and talented students work with us whenever they are available or free to do so. If you have any questions, comments, and/or concerns, please do not hesitate to email us at: rhochis@gmail.com.

With much gratitude,

The RCP Editorial Team
RHO CHI POST: EDITORIAL TEAM

@ Steve P. Soman (6th Year, STJ; Co-Editor-in-Chief)
Previously known as Ebey P. Soman, I really enjoy writing very opinionated articles. I strongly encourage all readers of our newsletter to respond with their own literary pieces. I look forward to hearing from you, and welcome your comments and constructive criticisms!

@ Neal Shah (6th Year, STJ; Co-Editor-in-Chief)
I frequently assist several professors on campus with their research. My goal is to provide my fellow students with research-based information that correlates with clinical pharmacotherapy. If you have any topics of interest or comments on currently-published articles, please do not hesitate to email me!

@ Addolorata Ciccone (6th Year, STJ; Co-Copy Editor [Content-Focused])
I am thrilled to serve as a Co-Copy Editor of Rho Chi Post. Whether you are brand new to the world of pharmacy, a seasoned veteran of this profession, or anywhere in between, I hope you find our work engaging, relatable, and informative. I look forward to reading your comments and feedback.

@ Bharat Kirthivasan (PhD Candidate, STJ; Co-Copy Editor [Content-Focused])
I am a doctoral candidate in Industrial Pharmacy researching nanoparticles for delivery to the brain. The only thing I enjoy more than reading a well-written piece of work is writing it. I am glad to work for the Rho Chi Post, and I encourage others to do the same.

@ Katharine Cimmino (4th Year, STJ; Co-Copy Editor [Content-Focused])
I have always been an avid reader and writer. As a co-copy editor of the Rho Chi Post I am able to merge my passions with the professionalism that comes with aspiring to be a healthcare provider. I am eager to be a part of a publication that promotes my interests and vocation.

@ Aleena Cherian (5th Year, STJ; Co-Copy Editor [Graphics-Focused])
The Rho Chi Post has been a source of current information and great advice to students and professionals in this evolving profession. After years of experience in media and graphics-related work, it is now my privilege to be a part of this endeavor as a Co-Copy Editor. I hope you learn as much from future editions of the newsletter as I have, and I welcome your feedback!

@ Mohamed J. Dungersi (6th Year, STJ; Senior Staff Editor)
I am enthusiastic about promoting the pharmacy profession, and what better way to do this than by being a part of the Rho Chi Post? Should you have any comments or concerns, feel free to contact me!
RHO CHI POST: EDITORIAL TEAM

@ Marie Huang (6th Year, STJ; Senior Staff Editor)
I am in a continuous process of self-definition, and constantly testing the boundaries of this world. I enjoy channeling my inspiration through words and photographs. As a witness to an evolving profession, I look forward to keeping you updated! Who knows where we will be tomorrow?

@ Mahdieh D. Yazdi (6th Year, STJ; Senior Staff Editor)
I like to stay current with all the changes in our profession, both legal and clinical. I hope to keep you informed with all that I learn. Please enjoy Rho Chi Post, and provide us detailed feedback so that we may improve our newsletter.

@ Shannon Tellier (6th Year, STJ; Senior Staff Editor)
I believe it is important for students and everyone else in the profession to stay informed about current pharmacy events. Rho Chi Post is a great way to continue learning information about what is happening on our campus and in the nation.

@ Erica Dimitropoulos (4th Year, STJ; Staff Editor)
As pharmacy students, we often fail to keep current with healthcare developments. My aim is to sort through the news and provide quick updates that are important to our profession. Feel free to contact me if there are any topics you would like to see covered in the next issue!

@ Tasnima Nabi (3rd Year, STJ; Staff Editor)
Writing has always been my greatest outlet for experience and knowledge, through which I hope to keep you engaged and informed. It is imperative to keep up with our changing profession and community, and I look forward to bringing pertinent information to the newsletter.

@ Tamara Yunusova (2nd Year, STJ; Staff Editor)
My name is Tamara Yunusova, and I am a 2nd year Pharm D candidate at St. John’s University. I enjoy articulating information in a captivating and insightful way. I hope to make this publication more informative, student-friendly, and innovative.

@ you!
We are looking for creative and motivated students to join the editorial team. If you are interested in becoming a full-time student editor, graphics editor or an assistant student editor for the Rho Chi Post, please contact us at rhochis@gmail.com!

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The Rho Chi Society encourages and recognizes excellence in intellectual achievement and advocates critical inquiry in all aspects of Pharmacy.

The Society further encourages high standards of conduct and character and fosters fellowship among its members.

The Society seeks universal recognition of its members as lifelong intellectual leaders in Pharmacy, and as a community of scholars, to instill the desire to pursue intellectual excellence and critical inquiry to advance the profession.

**THE RHO CHI POST**

**MISSION**
The Rho Chi Post is a monthly, electronic, student-operated, dean-approved publication that aims to promote the pharmacy profession through creativity and effective communication. Our publication is a profound platform for integrating ideas, opinions, and innovations from students, faculty, and administrators.

**VISION**
The Rho Chi Post aims to become the most exciting and creative student-operated newsletter within St. John’s University College of Pharmacy and Health Sciences. Our newsletter continues to be known for its relatable and useful content. Our editorial team continues to be known for its excellence and professionalism. The Rho Chi Post essentially sets the stage for the future of student-operated publications in pharmacy.

**VALUES**
Opportunity, Teamwork, Respect, Excellence

**GOALS**
1. To provide the highest quality student-operated newsletter with accurate information
2. To maintain a healthy, respectful, challenging, and rewarding environment for student editors
3. To cultivate sound relationships with other organizations and individuals who are like-minded and involved in like pursuits
4. To have a strong, positive impact on fellow students, faculty, and administrators
5. To contribute ideas and innovations to the Pharmacy profession

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  Place de la Porte Maillot côté Palais des Congrès, 75017, Paris

  Orlando World Center Marriott Resort & Convention Center
  Orlando, Florida

- Mar 26-27: Euro-Africa Health Investment Conference
  Institute of Physics, London, United Kingdom

- Apr 8-10: 3rd International Conference on Pharmaceutics & Novel Drug Delivery Systems
  Hilton Chicago/Northbrook,, Chicago, Illinois,

- Apr 9: CNS Orphan Diseases
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