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# Follow-On Biologics

*Garden of Eden, or a Shimmering Mirage?*

*Current Perspectives on the Law, Politics, and Science of Biogenerics, and What it Means for Patients and Industry*

BayBio

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## Why Are “Biogenerics” So Controversial?

- “Biologics” are a rapidly growing segment of medical care in the U.S.
- The cost to develop and manufacture biologics is substantially higher than for traditional “small molecule” drugs.
- Prices to patients are accordingly also very high.



## Why Are “Biogenerics” So Controversial?

- There is no regulatory pathway for the approval of “generic” biologics.
- Thus, even after patents expire, there is little prospect for competition from lower-cost alternatives.
- There also is no mechanism for challenging biologics patents in advance of marketing a potentially infringing product.
- Current generic drug laws inadequately protect innovators, who do not want to replicate that system for biologics



## Why are there no generic biologics?

- The generic drug approval statute (“Hatch-Waxman”) specifically applies only to versions of innovative drugs approved under section 505(b) of the FDCA;
- Biologics are approved under the PHSA, a separate statute from the FDCA.
- However, there are some “biologics” approved under FDCA for which generic approval may be possible.
- Highly complex molecules are difficult to characterize and produce



## What are “biologics” anyway?

- Generally speaking, therapeutic or diagnostic products consisting of, or derived from, living organisms.
- Statutorily speaking (PHSA):  
*“a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, ... applicable to the prevention, treatment, or cure of a disease or condition of human beings.”*



## What are “biologics” anyway?

- FDA authority extends beyond the PHS A-listed categories to include “analogous” products, including:
  - Therapeutic protein products (cytokines, interferons, enzymes, thrombolytics, etc.)
  - Monoclonal antibodies
  - Immunoglobulin products
  - Immunomodulators
  - Somatic cells
  - Human tissue and cellular products
  - Gene therapy products
  - Xenotransplantation products



## Biologics Approved Under FDCA

- Some products that are biologic in nature are nevertheless regulated and approved as drugs under the FDCA.
  - Human Growth Hormone
  - Insulin
  - Hyaluronidase
  - Menotropins
  - Glucagon
  - Salmon calcitonin
  
- For such NDA-approved “biologics,” a comparable competing product may be approved under a 505(b)(2) NDA, or theoretically an ANDA.



## Omnitrope (rhGH) 505(b)(2) NDA

- Sandoz sought approval of a 505(b)(2) NDA based in part on comparability to Genotropin.
- Pfizer petitioned FDA to require full clinical studies for Omnitrope, and argued that FDA's 505(b)(2) policy violated the FDCA and was unconstitutional.
- Sandoz sued FDA for delayed approval and court ordered a prompt FDA decision.
- FDA approved Omnitrope and denied Pfizer's petition 5/30/06. (<http://www.fda.gov/ohrms/dockets/dockets/04P0231/04P-0231-pdn0001.pdf>)



## FDA's "Historical Perspective" Article

**J. Woodcock, et al., *The FDA's Assessment of Follow-On Protein Products: a Historical Perspective*,  
Nature Reviews Drug Discovery (April 13, 2007).**

- Basic technical overview of protein products.
- Discussion of FDA history of reviews and approvals of follow-on protein products.
  - Non-recombinant (animal/human source) products.
  - Recombinant protein products.
  - Major manufacturing changes.



## FDA's "Historical Perspective" Article

- Non-recombinant (animal/human source) products
  - Albumin
  - Standardized allergenic extracts
  - Mammalian testicular hyaluronidase
  - DigiFab
- Recombinant protein products
  - Glucagon
  - Fortical (Salmon calcitonin nasal spray)
  - Omnitrope (rhGH)
  - Eprex (erythropoietin- $\alpha$ )
  - Recombivax HB (hepatitis B vaccine)
- Major manufacturing changes
  - Avonex (interferon  $\beta$ 1a)



## FDA's "Historical Perspective" Article

- Gives very general conclusions, not much direction:  
*"FDA will continue to integrate scientific advances and public health needs into its review of protein products."*
- *But, a couple teasers...*
- Teaser 1 (structure and mode of action):  
For some products, *"the primary mode of action...is not well understood, and its role in treatment was derived, in part, through trial and error. In such cases, even very extensive structural and functional comparisons between a follow-on and a comparable innovator product may not be sufficient to allow broad reliance on conclusions regarding a prior product."*



## FDA's "Historical Perspective" Article

### ➤ Teaser 2 (interchangeability):

*“To establish that two protein products would be substitutable, the sponsor of a follow-on product would need to demonstrate through additional clinical data that repeated switches from the follow-on product to the referenced product (and vice versa) would have no negative effect on the safety and/or effectiveness of the products as a result of immunogenicity. For many follow-on protein products – and in particular, the more complex proteins – there is a significant potential for repeated switches between products to have a negative impact on the safety and/or effectiveness. Therefore, the ability to make determinations of substitutability for follow-on protein products may be limited.”*



# Biogenerics Legislative Activity



# Biogenerics Legislation

- **“Access to Life-Saving Medicine Act”**
  - H.R. 1038, Waxman, 2/14/07;
  - S. 623, Schumer, 2/15/07
- **“Safety, Innovation, and Access to Medicines Act”**
  - Kennedy draft, 4/13/07
- **“Patient Protection and Innovative Biologic Medicines Act”**
  - H.R. 1956, Inslee, 4/19/07
- **Hearings**
  - Senate H.E.L.P., 3/8/07 (N. Rossignol, EU approach)
  - House Oversight & Government Reform, 3/26/07 (J. Woodcock)
  - House Energy & Commerce/Health Subcomm. (5/2/07)

## | *“Access to Life-Saving Medicine Act”*

- H.R. 1038, Waxman, 2/14/07
- A.K.A. the “Generic Wish List”
- Would create a new “Abbreviated Biological Product Application” (ABPA), and approval criteria and procedures.
- Three classes of products:
  - “Comparable” biologics
  - Comparable+Interchangeable biologics
  - Modified products (505(b)(2)-type approach)



## H.R. 1038 Comparability Criteria

➤ Follow-on biologic must be “comparable” to reference product. Comparable means:

*“absence of clinically meaningful differences between the biological product and the reference product in terms of the safety, purity and potency of the product”*



## H.R. 1038 Comparability Criteria

- Comparability evaluation based upon:
  - Chemical, physical, and biological assays, and other non-clinical laboratory studies;
  - Any necessary clinical studies to confirm safety, purity, and potency in one or more uses approved for reference product.
  - Data showing “comparable molecular structural features,” ***not including*** differences in heterogeneity profile, impurities, or degradation patterns.



## H.R. 1038 Comparability Presumptions

- Requires “highly similar principle molecular structural features;” but FDA must ignore the following differences:
  - For protein products: differences due to post-translational events, infidelity of translation/transcription, or minor differences in amino acid sequence, and for glycosylated proteins, different number of saccharide repeating units, or post-polymerization modifications.
  - For polysaccharide products: different number of saccharide repeating units, or differences in post-polymerization modifications.
  - For polynucleotide products: differences other than purine/pyrimidine bases bound to identical sugar backbone.



## H.R. 1038 Standard ABPA Criteria

- ABPA product must have:
- Same mechanism of action, if known, for a previously approved reference product indication.
  - Approval generally will be for all approved indications sharing the same mechanism of action (if known), even if applicant only showed comparability in a single indication.
- Same route of administration,
- Same dosage form,
- Same strength.
- But, these criteria not mandatory if other data shows Safety/Purity/Potency.



## H.R. 1038 Standard ABPA Criteria

- Manufacturing facilities must meet appropriate standards to assure safety, purity, and potency.
- Applicant may submit publicly available information regarding previous approval of innovator product.
- Applicant may submit any additional data supporting safety, purity, and potency.
- Failure to meet most approval criteria can be overcome by alternative data to show safety/purity/potency



## H.R. 1038 – Interchangeability

- “Interchangeable” means, with respect to a specific use, the product is
  - “comparable” to the reference product, and
  - “*can be expected to produce the same clinical result as the reference product in any given patient.*”



## H.R. 1038 – Interchangeability

- Applicant has option at any time to submit data in support of an interchangeability determination, but delay in interchangeability determination shall not delay initial approval with a non-interchangeable designation.
- Product approved with an interchangeability determination may indicate interchangeability with brand product in the product labeling.



## H.R. 1038 – ABPA Exclusivity

- First ABPA biologic to obtain interchangeability designation is awarded exclusivity delaying interchangeability determinations for subsequent ABPA products, and against “authorized generics,” but subsequent applicants can forego interchangeability request and not be blocked.
- Exclusivity ends at the earliest of:
  - 180 days after marketing;
  - 1 year after final favorable court decision or dismissal of patent litigation;
  - 36 months after approval if litigation unresolved;
  - 1 year after approval if no litigation.



## H.R. 1038 – Innovator Exclusivity

- No innovator exclusivities, i.e.,
  - No NCE/data exclusivity.
  - No 3-year new product/new use exclusivity.
  - No pediatric exclusivity.
  - No litigation stays of ABPA approval upon patent challenge.



## H.R. 1038 – ABPA Patent Challenges

- No mandatory patent certifications.
- Applicant may request BLA holder to disclose all patents that “relate to” the reference product, including patents claiming the compound, method of use, components, and method of manufacture.
- ABPA applicant *may, but is not required to*, provide patent notice at any time challenging the validity or non-infringement of any disclosed patents.
- Applicant may choose venue for litigation.



## H.R. 1038 – Patent Litigation

- BLA/patent holder may sue w/in 45 days:
  - Only in court chosen by ABPA applicant.
  - Only with respect to challenged patent(s).
- BLA/patent holder may not bring DJ action on patents not included in notice prior to sale.
- If suit not brought within 45 days of notice, or if dropped without decision or dismissal with prejudice, only remedy for infringement is a reasonable royalty.
- No suit allowed on patents that should have been, but were not, disclosed under ABPA request.

## *“Patient Protection and Innovative Biologic Medicines Act”*



- H.R. 1956 (Inslee, 4/19/07)
- A.K.A. the “Innovator Wish List”
- Procedures for “similar biological products,” based on existing FDA regulations for BLAs.
- Requires final product-class-specific guidances, upon request of applicant, issued through notice-and-comment, before submission of applications.
- Post-market safety monitoring mandatory.



## H.R. 1956

- Requires “proper name” unique to each manufacturer’s protein product.
- Requires label warning against substitution without express physician authorization.
- Prohibits therapeutic equivalence ratings, but requires future reports to Congress on feasibility and standards for allowing equivalence ratings.
- No application filed until 12 years after innovator approval, and no application approved until 14 years after original approval (15 years if innovator receives new indication).



# Kennedy Draft Legislation

## ***“Safety, Innovation, and Access to Medicines Act”*** ***(Staff Discussion Draft 4/13/07)***

- Gives FDA broader discretion than HR 1038.
- Higher standards for comparability/ interchangeability.
- Two types of NCE Exclusivity.
- Transitional exclusivity.
- Litigation stay of approval.
- Data exclusivity option in lieu of patent protection.
- Pediatric exclusivity available.
- Exclusivity extensions for approval of clinically significant new uses.



# Kennedy Draft Legislation

## ➤ Comparability

- Same or “highly similar” active ingredient.
- No clinically meaningful differences in safety, purity, or potency.
- Thorough characterization of molecular structural features.
- Assays, animal models (pharmacologic, PD, PK, Tox), “any necessary clinical trials,” mechanism of action data.



# Kennedy Draft Legislation

- Comparability Guidances
  - General guidance shall be issued within 2 years.
  - Product class-specific guidances may be issued.
  - Negative Guidances may be issued where current science and experience does not allow approval of comparable products
- Lack of Guidance does not bar application.



# Kennedy Draft Legislation

- Interchangeability criteria:
  - Data to show that product is expected to produce same clinical result in any given patient for the same indication.
  - No expected adverse effects, including immunogenicity, when patients are switched between innovator and follow-on products.
  - Follow-on label must state lack of interchangeability on a per-indication basis where applicable.
- No interchangeability decisions before general guidance issued, or 2 years.



# Kennedy Draft Legislation

## ➤ NCE Exclusivity

- Different periods depending on whether reference product approval based on clinical studies.
- Exclusivity blocks submission of follow-on application (but can file 1 year early with patent challenge).
- Extra exclusivity available if new use approved that has “significant clinical benefit” compared to existing products.



# Kennedy Draft Legislation

- **Exclusivity in Lieu of Patent Protection**
  - Innovator can submit notice to FDA that any patents will not be enforced against comparable product sponsors. Creates royalty-free license.
  - Such notice would give longer exclusivity than the statute's NCE exclusivity.
  - Can be extended if new use approved that has “significant clinical benefit” compared to existing products.



# Kennedy Draft Legislation

- **Transitional Exclusivity**
  - For pre-enactment biologics, follow-on approvals barred for  $x$  years, minus # of days between original approval and enactment.
  - Does not apply if there is a right of reference.
- **Pediatric Exclusivity.**
  - Would apply to biologics in same way as under current law for drugs.



## Kennedy Draft Legislation

- Patent Challenges and Approval Stay
  - ABPA applicant tells FDA it will challenge patent; Notifies innovator of filing and gives offer of confidential access to application.
  - Innovator may then send patent list to applicant.
  - Applicant can then challenge patent(s) identified by innovator, or other patents identified by applicant.
  - If innovator sues, additional time added to NCE exclusivity periods.
  - Listings and pleadings must be submitted to FTC.



## Implications

- Prospect for some legislation seems strong.
- Compromise approach will be necessary, with meaningful innovator protections.
- Innovator/Generic industry distinctions will be blurred.



# Implications

- Under any approach, biogenerics –
  - Will not be easy to make or get approved;
  - In most cases are still a long way off, even with a pathway;
  - Will rarely be interchangeable;
  - Will be difficult to market without a branded-type approach;
  - Will have less cost-savings than traditional generics;
  - Will continue to be a political lightning rod.

**James N. Czaban** is a Partner in the FDA Department at Wilmer Cutler Pickering Hale & Dorr LLP in Washington, D.C., where he serves the firm’s pharmaceutical, biotechnology, and other life sciences clients in all aspects of pharmaceutical regulation, including FDA approvals, Hatch-Waxman and lifecycle management strategies, FDA compliance, and federal and state enforcement matters. He also advises pharmaceutical and biotechnology companies on promotional compliance, legislative strategies and advocacy, administrative litigation, SEC-regulated corporate disclosure issues, and regulatory due diligence. Mr. Czaban has been named a “Top Lawyer” in Food and Drug Law by *Washingtonian* magazine, and is a frequent author and speaker on topics of FDA regulation of therapeutic products. He received his JD from the University of Virginia School of Law and his BA from the University of California, Berkeley.

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# SEC/FDA DISCLOSURE COOPERATION

Brian Cunningham, CEO  
Trellis Bioscience, Inc.

April 26, 2007

BayBio Annual Meeting

# ORIGIN OF THE COOPERATION

- February 2004 Memorandum of Understanding (MOU) between FDA and SEC
  - Formalized procedures for FDA/SEC sharing of non-public information
- 2004 MOU instituted five significant changes at FDA
  - Established centralized referral procedure
    - FDA is not the “health SEC”
  - Established liaison officers
  - Established FDA/SEC cross-training
  - Email to be utilized where appropriate
  - Blanket authorization under 21 C.F.R. § 20.85

# PREVIOUS LACK OF SEC SOPHISTICATION

- Experience while at Genentech in 1980s
- Call from the SEC branch chief
- “Impounded” Genentech’s TPA NDA
- Complaints from investors in R&D Partnership of understated value
- Discussion of a novel formulation and delivery method

# SEC Reads the Newspapers

- I pointed out
  - Novel formulation
    - Highly speculative
    - Difficult and complicated disclosure
  - That FDA approval could not be assumed
- SEC Branch Chief response
  - “We read the newspapers”
  - “Everyone knows the Advisory Committee meets next week to recommend approval”

# ADVISORY COMMITTEE RESULT

- Advisory Committee recommended against approval
- SEC never called again

# NOT CURRENTLY A HOT TOPIC

- Securities attorneys generally unaware of FDA involvement in review of filings with SEC
- They report no significant issues
- They think it has made no difference
- FDA attorneys report differently

# FDA ATTORNEYS' EXPERIENCE

- FDA attorneys report noticeable increase in sophistication of comments from the SEC concerning filings with the FDA
- No specific assignment of FDA personnel to monitor SEC filings

# INTERPRETIVE CHALLENGE

- Complete Response Letter
  - Can run to 35 pages
  - Dozens of questions
- Can it be characterized simply?
- As positive or negative?
- Can all the questions be answered with data already in hand?
- Is an additional clinical trial required?



# Expanded Access to Investigational Drugs for Treatment Use

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Ginny Beakes-Read  
Genentech



# Discussion Areas

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- Background
- 2007 Proposed Rule
- Court Case
- Legislation
- Practical Effect



# Expanded Access – Background

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- Treatment use vs. investigational use
  - Limited use for serious diseases with no satisfactory alternatives
- Balance early access of promising drug with need to develop and approve drug
- Longstanding Agency practice
- In FDA regulations in 1987



# 1987 Regulations

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- Described two categories of INDs
  - Treatment IND
  - Emergency Use IND
- Goal was to improve access to certain investigational drugs by expressly authorizing the INDs and clarifying the process to obtain the drug



# Purpose for Legislation

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- To show that “opportunities to participate in expanded access programs are available to every individual with a life-threatening or seriously debilitating illness for which there is not an effective, approved therapy.”



# FDAMA - Addressed Continued Criticism of FDA:

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- Failure to explain basis for decisionmaking on treatment use
- Disparate access to treatment use
  - Physicians in academic medical centers more familiar with rules get drugs for patients
  - Certain disease types focused on (oncology, HIV-related conditions)



# 2007 Proposed Rules

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- To address same concerns that motivated Congress
- Legislation didn't require rulemaking, but regulations help by creating more more specific procedures and explaining the rationale behind the provisions



# Proposed Rules – Purpose

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- Clarify, and thereby expand, access to certain unapproved drugs
- Balance individuals' rights to health care decisions with society's need for marketed drug
- Balance risks and benefits to protect patients from unacceptable risks



# Major Change to Current Regulations

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- Added Intermediate Size Population
  - From 10-100 patients
  - FDA can ask sponsors to consolidate individual patient INDs
  - Trying to collect more information, reduce administrative burden



# Significant Provisions

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- Explicitly describes evidentiary requirements for each category
  - Sliding scale: more evidence of safety/efficacy needed as size of population increases
  - More evidence needed for “serious” disease than for “immediately life threatening” disease
- Clarifies that continuation studies are not considered treatment use



# Significant Provisions - cont.

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- FDA views sponsors' use of open-label safety studies as way to avoid classifying IND as a treatment IND
  - Large population
  - Limited collection of data
  - Studies may not be designed to generate data to meaningfully assess safety endpoints



# Criteria for all Expanded Access Uses

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- Patient must have serious or life-threatening disease/condition and there is no comparable or satisfactory alternative therapy
- FDA must determine that the potential benefit justifies the potential risks and that the risks are not unreasonable in the context of the disease treated



# Criteria for all Expanded Access Uses – cont.

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- FDA must determine that providing investigational drug will not interfere with the initiation, conduct, or completion of clinical investigations that could support marketing of the expanded access use



# Safeguards - All Expanded Use Categories

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- Licensed physician directing drug administration is the *investigator* with all responsibilities
- Individual or entity submitting IND is the *sponsor* with all responsibilities
- A licensed physician may be both the sponsor and investigator



# Individual Patient – Submission Requirements

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- If existing IND, submission can be made by sponsor or physician
  - Sponsors are encouraged to amend INDs to include individual patient expanded access protocols
- For new IND, physician may obtain sponsor permission for FDA to reference information in sponsor's IND



# Individual Patient - Safeguards

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- Generally limited to a single course of therapy for specified duration
- If extended duration, FDA may require sponsors to monitor patient
- Sponsor/physician must submit written summary of results, AEs, at end of treatment



# Individual Patient - Emergency

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- Expanded access may be authorized by FDA medical review officer
- Request may be sent by phone, email, fax
- Sponsor/physician must explain how the expanded access meets the requirements and agree to send written submission within 5 working days



# Intermediate Size Population

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- May use if drug not being developed (e.g., rare disease)
- May use if drug being developed, but patients are unable to participate in the trial (different disease, stage, not meet enrollment criteria, enrollment closed, trial site not accessible)



# Intermediate Size Population

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- May use for approved or related drug
  - Approved drug no longer marketed for safety reasons or unavailable b/c failed to meet application requirements (GMP)
  - Drug with the same active moiety as an approved drug unavailable through failure to meet application requirements or because of drug shortage
    - Must not pose unreasonable risk



# Intermediate Size Population

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- FDA may ask sponsor to consolidate individual patient INDs after a “significant number” of requests
  - Probably between 10-100 requests
  - Varies depending on indication, number of patients with no available therapeutic options, extent to which drug has potential to benefit patients
  - If 10 requests for same use in short time (<6 mos), FDA will consider whether to ask a potential sponsor to submit intermediate size protocol/IND



# Intermediate Size - Criteria

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- Enough evidence that drug is safe at dose/duration proposed
  - More evidence than needed for individual patient because more people exposed
- At least preliminary evidence of effectiveness or of a plausible pharmacologic effect



# Intermediate Size - Safeguards

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- FDA will review IND annual report to see if appropriate to continue expanded access
- If not being actively developed, FDA will consider whether expanded access is interfering with clinical development
- As enrollment increases, FDA will consider whether to request the sponsor to submit a treatment IND
- Sponsor must monitor investigators for compliance with protocol



# Treatment IND - Criteria

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- Drug is being investigated in controlled clinical trial designed to support marketing application for the use, or
- All clinical trials have been completed.
- Sponsor must be actively pursuing marketing approval of use with due diligence



# Treatment IND - Criteria

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- With **serious disease or condition**, must have sufficient clinical evidence of safety and efficacy to support use
  - Usually from phase 3 trials, but could be compelling data from phase 2 trials



# Treatment IND - Criteria

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- With **immediately life-threatening disease or condition**, available scientific evidence provides a reasonable basis to conclude that the drug may be effective for the use and would not expose patients to unreasonable or significant risk of illness or injury
  - Usually data from phase 3 or phase 2 trials, but could be more preliminary



# Treatment Use - Safeguards

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- Sponsor is responsible for monitoring the treatment protocol to ensure that licensed physicians comply with the protocol and the regulations applicable to investigators



# Court Case

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- Abigail Alliance v. von Eschenbach, 445 F.3d 470 (D.C. Cir. 2006)
  - DC Court of Appeals – May 2006
  - Reheard by full Court – March 2007
- Established limited Constitutional right
  - Terminally ill patients, post-phase I investigational drug, all other approved options exhausted



# Many Issues, including...

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- Why just for terminally ill? And how to define that group?
- Can the line of post-phase I be defended?
- Limit only to mentally competent?
- What is potentially life-saving?



# What Next?

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- Eventually will end up in US Supreme Court
- In meantime, FDA will likely finalize rules
- Legislation unlikely, though Bill drafted



# Legislation

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- Senator Sam Brownback (R-KS) introduced legislation in 109<sup>th</sup> Congress
- ACCESS Act, S. 1956
- To create a “new three-tiered approval system for drugs, biological products, and devices” responsive to needs of seriously ill patients
- Modeled on Abigail Alliance proposal



# Practical Effect

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- Manufacturers not forced to provide drug, but increased pressure to do so
- Public awareness of issues – rising expectations when promising results
  - Trial sites, websites/blogs, information sharing
  - Patient advocacy groups
  - Media coverage of health issues



# Practical Effect

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- Company's desire to get drug marketed, need adequate trial population
- May not have supply available for expanded access and clinical trial
  - Could provide through lottery for limited participants
- Liability concerns with providing investigational drugs



# Practical Effect – Who pays for the Expanded Access?

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- When charging for investigational drugs is permitted, how much can be charged?
  - Proposed rule doesn't allow for profit; some disagree and believe sponsors need incentive
- Proposed Rule treats charging in clinical trials differently from charging in expanded access program
  - Allows only direct costs for clinical trials
  - Allows for administrative costs of running expanded access program

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