What is claimed is:

1. A method for preparation of a medicament to improve the efficacy and/or reduce the side effects of suboptimally administered drug therapy comprising the steps of:

(a) identifying at least one factor or parameter associated with the efficacy and/or occurrence of side effects of the drug therapy; and

(b) modifying the factor or parameter to improve the efficacy and/or reduce the side effects of the drug therapy by preparation of a medicament according to the modified factor or parameter;

wherein the medicament employed in the suboptimally administered drug therapy is ~~a substituted hexitol~~dianhydrogalactitol.

2. The method of claim 1 wherein the factor or parameter is selected from the group consisting of:

(a) dose modification;
(b) route of administration;
(c) schedule of administration;
(d) indications for use;
(e) selection of disease stage;
(f) other indications;
(g) patient selection;
(h) patient/disease phenotype;
(i) patient/disease genotype;
(j) pre/post-treatment preparation
(k) toxicity management;
(l) pharmacokinetic/pharmacodynamic monitoring;
(m) drug combinations;
(n) chemosensitization;
(o) chemopotentiation;
(p) post-treatment patient management;
(q) alternative medicine/therapeutic support;
(r) bulk drug product improvements;
(s) diluent systems;
(t) solvent systems;
(u) excipients;
(v) dosage forms;
(w) dosage kits and packaging;
(x) drug delivery systems;
(y) drug conjugate forms;
(z) compound analogs;
(aa) prodrugs;
(ab) multiple drug systems;
(ac) biotherapeutic enhancement;
(ad) biotherapeutic resistance modulation;
(ae) radiation therapy enhancement;
(af) novel mechanisms of action; and
(ag) selective target cell population therapeutics.

3. The method of claim 1 wherein the drug therapy is administered to treat a hyperproliferative disease.

4. The method of claim 3 wherein the hyperproliferative disease is cancer.

~~5. The method of claim 1 wherein the substituted hexitol is selected from the group consisting of dianhydrogalactitol and a derivative thereof.~~

~~6. The method of claim 5 wherein the substituted hexitol is dianhydrogalactitol.~~

~~7. The method of claim 1 wherein the substituted hexitol is selected from the group consisting of diacetyldianhydrogalactitol and a derivative thereof.~~

~~8. The method of claim 7 wherein the substituted hexitol is diacetyldianhydrogalactitol.~~

~~9~~5. The method of claim 2 wherein the improvement is made by dose modification~~, wherein the suboptimally administered drug therapy comprises administration of dianhydrogalactitol, and the preparation of a medicament is for use with a dose modification~~.

~~10~~6. The method of claim ~~9~~ 5 wherein the dose modification is a modification selected from the group consisting of:

(i) continuous i.v. infusion for hours to days;
(ii) biweekly administration;
(iii) doses greater than 5 mg/m^2/day;
(iv) progressive escalation of dosing from 1 mg/m^2/day based on patient tolerance;
(v) use of caffeine to modulate metabolism;
(vi) use of isonazid to modulate metabolism;
(vii) selected and intermittent boosting of dosage administration;
(viii) administration of single and multiple doses escalating from 5 mg/m^2/day via bolus;
(ix) oral dosages of below 30 mg/m^2; and
(x) oral dosages of above 130 mg/m^2.

~~11. The method of claim 2 wherein the improvement is made by dose modification, wherein the suboptimally administered drug therapy comprises administration of diacetyldianhydrogalactitol, and the preparation of a medicament is for use with a dose modification.~~

~~12. The method of claim 11 wherein the dose modification is a modification selected from the group consisting of:~~

~~(i) continuous i.v. infusion for hours to days;~~
~~(ii) biweekly administration;~~
~~(iii) doses greater than 5 mg/m^2/day;~~

~~(iv) progressive escalation of dosing from 1 mg/m^2/day based on patient tolerance;~~

~~(v) use of caffeine to modulate metabolism;~~

~~(vi) use of isonazid to modulate metabolism;~~

~~(vii) selected and intermittent boosting of dosage administration;~~

~~(viii) administration of single and multiple doses escalating from 5 mg/m^2/day via bolus;~~

~~(ix) oral dosages of below 30 mg/m^2; and~~

~~(x) oral dosages of above 130 mg/m^2.~~

~~13~~7. The method of claim 2 wherein the improvement is made by the route of administration~~, wherein the suboptimally administered drug therapy comprises administration of dianhydrogalactitol, and the preparation of the medicament is for use by a route of administration~~.

~~14~~8. The method of claim ~~13~~ 7 wherein the route of administration is selected from the group consisting of:

(i) topical administration;
(ii) intravesicular administration for bladder cancer;
(iii) oral administration;
(iv) slow release oral delivery;
(v) intrathecal administration;
(vi) intraarterial administration;
(vii) continuous infusion; and
(ix) intermittent infusion.

~~15. The method of claim 2 wherein the improvement is made by the route of administration, wherein the suboptimally administered drug therapy comprises administration of diacetyldianhydrogalactitol, and the preparation of the medicament is for use by a route of administration.~~

~~16. The method of claim 15 wherein the route of administration is selected from the group consisting of:~~

~~(i) topical administration;~~

~~(ii) intravesicular administration for bladder cancer;~~

~~(iii) oral administration;~~

~~(iv) slow release oral delivery;~~

~~(v) intrathecal administration;~~

~~(vi) intraarterial administration;~~

~~(vii) continuous infusion; and~~

~~(ix) intermittent infusion.~~

~~17~~9. The method of claim 2 wherein the improvement is made by the schedule of administration~~, wherein the suboptimally administered drug therapy comprises administration of dianhydrogalactitol, and the preparation of the medicament is for use according to a schedule of administration~~.

~~18~~10. The method of claim ~~17~~ 9 wherein the schedule of administration is selected from the group consisting of:

(i) daily administration;
(ii) weekly administration;
(iii) weekly administration for three weeks;
(iv) biweekly administration;
(v) biweekly administration for three weeks with a 1-2 week rest period;
(vi) intermittent boost dose administration; and
(vii) daily administration for one week for multiple weeks.

~~19. The method of claim 2 wherein the improvement is made by the schedule of administration, wherein the suboptimally administered drug therapy comprises administration of diacetyldianhydrogalactitol, and the preparation of the medicament is for use according to a schedule of administration.~~

~~20. The method of claim 19 wherein the schedule of administration is selected from the group consisting of:~~

~~(i) daily administration;~~
~~(ii) weekly administration;~~
~~(iii) weekly administration for three weeks;~~
~~(iv) biweekly administration;~~
~~(v) biweekly administration for three weeks with a 1-2 week rest period;~~
~~(vi) intermittent boost dose administration; and~~
~~(vii) daily administration for one week for multiple weeks.~~

~~21~~11. The method of claim 2 wherein the improvement is made by the indication for use~~, wherein the suboptimally administered drug therapy comprises administration of dianhydrogalactitol, and wherein the preparation of the medicament is for use with an indication for use~~.

~~22~~12. The method of claim ~~21~~ 11 wherein the indication for use is selected from the group consisting of:

(i) use for treatment of leukemias;
(ii) use for treatment of myelodysplastic syndrome;
(iii) use for treatment of angiogenic diseases;
(iv) use for treatment of benign prostatic hyperplasia;
(v) use for treatment of psoriasis;
(vi) use for treatment of gout;
(vii) use for treatment of transplantation rejections;
(viii) use for prevention of restenosis in cardiovascular disease;
(ix) use for treatment of mycosis fungoides;
(x) use in bone marrow transplantation;
(xi) use as an anti-infective agent;
(xii) use for treatment of AIDS; and
(xiii) use for treatment of lymphoma.

~~23. The method of claim 2 wherein the improvement is made by the indication for use, wherein the suboptimally administered drug therapy comprises administration of diacetyldianhydrogalactitol, and wherein the preparation of the medicament is for use with an indication for use.~~

~~24. The method of claim 23 wherein the indication for use is selected from the group consisting of:~~

~~(i) use for treatment of leukemias;~~
~~(ii) use for treatment of myelodysplastic syndrome;~~
~~(iii) use for treatment of angiogenic diseases;~~
~~(iv) use for treatment of benign prostatic hyperplasia;~~
~~(v) use for treatment of psoriasis;~~
~~(vi) use for treatment of gout;~~
~~(vii) use for treatment of transplantation rejections;~~
~~(viii) use for prevention of restenosis in cardiovascular disease;~~
~~(ix) use for treatment of mycosis fungoides;~~
~~(x) use in bone marrow transplantation;~~
~~(xi) use as an anti-infective agent;~~
~~(xii) use for treatment of AIDS; and~~
~~(xiii) use for treatment of lymphoma.~~

~~25~~13. The method of claim 2 wherein the improvement is made by selection of disease stage~~, wherein the suboptimally administered drug therapy comprises administration of dianhydrogalactitol, and wherein the preparation of a medicament is for use in a selected disease stage~~.

~~26~~14. The method of claim ~~25~~ 13 wherein the selection of disease stage is selected from the group consisting of:

(i) use for the treatment of localized polyp stage colon cancer;
(ii) use for leukoplakia in the oral cavity;
(iii) use for angiogenesis inhibition to prevent or limit metastatic spread of a malignancy; and
(iv) use for treatment of HIV with a therapy selected from the group consisting of azidothymidine (AZT), dideoxyadenosine (DDI), and reverse transcriptase inhibitors.

~~27. The method of claim 2 wherein the improvement is made by selection of disease stage, wherein the suboptimally administered drug therapy comprises administration of diacetyldianhydrogalactitol, and wherein the preparation of a medicament is for use in a selected disease stage.~~

~~28. The method of claim 27 wherein the selection of disease stage is selected from the group consisting of:~~

~~(i) use for the treatment of localized polyp stage colon cancer;~~
~~(ii) use for leukoplakia in the oral cavity;~~

~~(iii) use for angiogenesis inhibition to prevent or limit metastatic spread of a malignancy; and~~

~~(iv) use for treatment of HIV with a therapy selected from the group consisting of azidothymidine (AZT), dideoxyadenosine (DDI), and reverse transcriptase inhibitors.~~

~~29~~15. The method of claim 2 wherein the improvement is made by ~~selection of disease stage, wherein the suboptimally administered drug therapy comprises administration of dianhydrogalactitol, and wherein the preparation of a medicament is for use in an indication that is one of~~ other indications.

~~30~~16. The method of claim ~~29~~ 15 wherein the other indication is selected from the group consisting of:

(i) use as an anti-infective agent;
(ii) use as an antiviral agent;
(iii) use as an antibacterial agent;
(iv) use as an agent to treat pleural effusion;
(v) use as an antifungal agent;
(vi) use as an anti-parasitic agent;
(vii) use as an agent to treat eczema;
(viii) use as an agent to treat herpes zoster (shingles);
(ix) use as an agent to treat condylomata;
(x) use as an agent to treat HPV; and
(xi) use as an agent to treat HSV.

~~31. The method of claim 2 wherein the improvement is made by selection of disease stage, wherein the suboptimally administered drug therapy comprises administration of diacetyldianhydrogalactitol, and wherein the preparation of a medicament is for use in an indication that is one of other indications.~~

~~32. The method of claim 31 wherein the other indication is selected from the group consisting of:~~

~~(i) use as an anti-infective agent;~~
~~(ii) use as an antiviral agent;~~
~~(iii) use as an antibacterial agent;~~
~~(iv) use as an agent to treat pleural effusion;~~
~~(v) use as an antifungal agent;~~
~~(vi) use as an anti-parasitic agent;~~
~~(vii) use as an agent to treat eczema;~~
~~(viii) use as an agent to treat herpes zoster (shingles);~~
~~(ix) use as an agent to treat condylomata;~~
~~(x) use as an agent to treat HPV; and~~
~~(xi) use as an agent to treat HSV.~~

~~33~~17. The method of claim 2 wherein the improvement is made by patient selection~~, wherein the suboptimally administered drug therapy comprises administration of~~

~~dianhydrogalactitol, and wherein the preparation of a medicament is for use according to patient selection~~.

~~34~~18. The method of claim ~~33~~ 17 wherein the patient selection is carried out by a criterion selected from the group consisting of:

(i) selecting patients with a disease condition characterized by a high level of a metabolic enzyme selected from the group consisting of histone deacetylase and ornithine decarboxylase;

(ii) selecting patients with a low or high susceptibility to a condition selected from the group consisting of thrombocytopenia and neutropenia;

(iii) selecting patients intolerant of GI toxicities; and

(iv) selecting patients characterized by over- or under-expression of a gene selected from the group consisting of c-Jun, a GPCR, a signal transduction protein, VEGF, a prostate-specific gene, and a protein kinase.

~~35. The method of claim 2 wherein the improvement is made by patient selection, wherein the suboptimally administered drug therapy comprises administration of diacetyldianhydrogalactitol, and wherein the preparation of a medicament is for use according to patient selection.~~

~~36. The method of claim 35 wherein the patient selection is carried out by a criterion selected from the group consisting of:~~

~~(i) selecting patients with a disease condition characterized by a high level of a metabolic enzyme selected from the group consisting of histone deacetylase and ornithine decarboxylase;~~

~~(ii) selecting patients with a low or high susceptibility to a condition selected from the group consisting of thrombocytopenia and neutropenia;~~

~~(iii) selecting patients intolerant of GI toxicities; and~~

~~(iv) selecting patients characterized by over- or under-expression of a gene selected from the group consisting of c-Jun, a GPCR, a signal transduction protein, VEGF, a prostate-specific gene, and a protein kinase.~~

~~37~~19. The method of claim 2 wherein the improvement is made by analysis of patient or disease phenotype~~, wherein the suboptimally administered drug therapy comprises administration of dianhydrogalactitol, and wherein the preparation of a medicament is for use according to an analysis of patient or disease phenotype~~.

~~38~~20. The method of claim ~~37~~ 19 wherein the analysis of patient or disease phenotype is carried out by a method selected from the group consisting of:

(i) use of a diagnostic tool, a diagnostic technique, a diagnostic kit, or a diagnostic assay to confirm a patient's particular phenotype;

(ii) use of a method for measurement of a marker selected from the group consisting of histone deacetylase, ornithine decarboxylase, VEGF, a protein that is a gene product of a prostate specific gene, a protein that is a gene product of jun, and a protein kinase;

(iii) surrogate compound dosing; and

(iv) low dose pre-testing for enzymatic status.

~~39. The method of claim 2 wherein the improvement is made by analysis of patient or disease phenotype, wherein the suboptimally administered drug therapy comprises administration of diacetyldianhydrogalactitol, and wherein the preparation of a medicament is for use according to an analysis of patient or disease phenotype.~~

~~40. The method of claim 39 wherein the analysis of patient or disease phenotype is carried out by a method selected from the group consisting of:~~

~~(i) use of a diagnostic tool, a diagnostic technique, a diagnostic kit, or a diagnostic assay to confirm a patient's particular phenotype;~~

~~(ii) use of a method for measurement of a marker selected from the group consisting of histone deacetylase, ornithine decarboxylase, VEGF, a protein that is a gene product of a prostate specific gene, a protein that is a gene product of jun, and a protein kinase;~~

~~(iii) surrogate compound dosing; and~~

~~(iv) low dose pre-testing for enzymatic status.~~

~~41~~21. The method of claim 2 wherein the improvement is made by analysis of patient or disease genotype~~, wherein the suboptimally administered drug therapy comprises administration of dianhydrogalactitol, wherein the preparation of a medicament is for use according to an analysis of patient or disease genotype~~.

~~42~~22. The method of claim ~~41~~ 21 wherein the analysis of patient or disease genotype is carried out by a method selected from the group consisting of:

(i) use of a diagnostic tool, a diagnostic technique, a diagnostic kit, or a diagnostic assay to confirm a patient's particular genotype;

(ii) use of a gene chip;

(iii) use of gene expression analysis;

(iv) use of single nucleotide polymorphism (SNP) analysis; and

(v) measurement of the level of a metabolite or a metabolic enzyme.

~~43~~23. The method of claim ~~42~~ 22 wherein the method is the use of single nucleotide polymorphism (SNP) analysis and the SNP analysis is carried out on a gene selected from the group consisting of histone deacetylase, ornithine decarboxylase, VEGF, a prostate specific gene, c-Jun, and a protein kinase.

~~44. The method of claim 2 wherein the improvement is made by analysis of patient or disease genotype, wherein the suboptimally administered drug therapy comprises administration of diacetyldianhydrogalactitol, wherein the preparation of a medicament is for use according to an analysis of patient or disease genotype.~~

~~45. The method of claim 44 wherein the analysis of patient or disease genotype is carried out by a method selected from the group consisting of:~~

~~(i) use of a diagnostic tool, a diagnostic technique, a diagnostic kit, or a diagnostic assay to confirm a patient's particular genotype;~~

~~(ii) use of a gene chip;~~

~~(iii) use of gene expression analysis;~~

~~(iv) use of single nucleotide polymorphism (SNP) analysis; and~~

~~(v) measurement of the level of a metabolite or a metabolic enzyme.~~

~~46. The method of claim 45 wherein the method is the use of single nucleotide polymorphism (SNP) analysis and the SNP analysis is carried out on a gene selected from the group consisting of histone deacetylase, ornithine decarboxylase, VEGF, a prostate specific gene, c-Jun, and a protein kinase.~~

~~47~~24. The method of claim 2 wherein the improvement is made by pre/post treatment preparation~~, wherein the suboptimally administered drug therapy comprises administration of dianhydrogalactitol, and wherein preparation of a medicament is for use with pre/post treatment preparation~~.

~~48~~25. The method of claim ~~47~~ 24 wherein the pre/post treatment preparation is selected from the group consisting of:

(i) the use of colchicine or an analog thereof;
(ii) the use of a uricosuric;
(iii) the use of uricase;
(iv) the non-oral use of nicotinamide;
(v) the use of a sustained-release form of nicotinamide;
(vi) the use of an inhibitor of poly-ADP ribose polymerase;
(vii) the use of caffeine;
(viii) the use of leucovorin rescue;
(ix) infection control; and
(x) the use of an anti-hypertensive agent.

~~49~~26. The method of claim ~~48~~ 25 wherein the pre/post treatment is the use of a uricosuric and wherein the uricosuric is probenecid or an analog thereof.

~~50. The method of claim 2 wherein the improvement is made by pre/post treatment preparation, wherein the suboptimally administered drug therapy comprises administration of diacetyldianhydrogalactitol, and wherein preparation of a medicament is for use with pre/post treatment preparation.~~

~~51. The method of claim 50 wherein the pre/post treatment preparation is selected from the group consisting of:~~

~~(i) the use of colchicine or an analog thereof;~~
~~(ii) the use of a uricosuric;~~
~~(iii) the use of uricase;~~
~~(iv) the non-oral use of nicotinamide;~~
~~(v) the use of a sustained-release form of nicotinamide;~~
~~(vi) the use of an inhibitor of poly-ADP ribose polymerase;~~
~~(vii) the use of caffeine;~~
~~(viii) the use of leucovorin rescue;~~
~~(ix) infection control; and~~
~~(x) the use of an anti-hypertensive agent.~~

~~52. The method of claim 51 wherein the pre/post treatment is the use of a uricosuric and wherein the uricosuric is probenecid or an analog thereof.~~

~~53~~27. The method of claim 2 wherein the improvement is made by toxicity management~~, wherein the suboptimally administered drug therapy comprises administration of dianhydrogalactitol, and wherein the preparation of a medicament is for use with toxicity management~~.

~~54~~28. The method of claim ~~53~~ 27 wherein the toxicity management is selected from the group consisting of:

(i) the use of colchicine or an analog thereof;
(ii) the use of a uricosuric;
(iii) the use of uricase;
(iv) the non-oral use of nicotinamide;
(v) the use of a sustained-release form of nicotinamide;
(vi) the use of an inhibitor of poly-ADP ribose polymerase;
(vii) the use of caffeine;
(viii) the use of leucovorin rescue;
(ix) the use of sustained-release allopurinol;
(x) the non-oral use of allopurinol;
(xi) the use of bone marrow transplants;
(xii) the use of a blood cell stimulant;
(xiii) the use of blood or platelet infusions;
(xiv) the administration of an agent selected from the group consisting of filgrastim, G-CSF, and GM-CSF;
(xv) the application of a pain management technique;
(xvi) the administration of an anti-inflammatory agent;
(xvii) the administration of fluids;
(xviii) the administration of a corticosteroid;
(xix) the administration of an insulin control medication;
(xx) the administration of an antipyretic;
(xxi) the administration of an anti-nausea treatment;
(xxii) the administration of an anti-diarrheal treatment;
(xxiii) the administration of N-acetylcysteine; and
(xxiv) the administration of an antihistamine.

~~55. The method of claim 2 wherein the improvement is made by toxicity management, wherein the suboptimally administered drug therapy comprises administration of diacetyldianhydrogalactitol, and wherein the preparation of a medicament is for use with toxicity management.~~

~~56. The method of claim 55 wherein the toxicity management is selected from the group consisting of:~~

~~(i) the use of colchicine or an analog thereof;~~
~~(ii) the use of a uricosuric;~~
~~(iii) the use of uricase;~~
~~(iv) the non-oral use of nicotinamide;~~
~~(v) the use of a sustained-release form of nicotinamide;~~
~~(vi) the use of an inhibitor of poly-ADP ribose polymerase;~~

~~(vii) the use of caffeine;~~
~~(viii) the use of leucovorin rescue;~~
~~(ix) the use of sustained-release allopurinol;~~
~~(x) the non-oral use of allopurinol;~~
~~(xi) the use of bone marrow transplants;~~
~~(xii) the use of a blood cell stimulant;~~
~~(xiii) the use of blood or platelet infusions;~~
~~(xiv) the administration of an agent selected from the group consisting of filgrastim, G-CSF, and GM-CSF;~~
~~(xv) the application of a pain management technique;~~
~~(xvi) the administration of an anti-inflammatory agent;~~
~~(xvii) the administration of fluids;~~
~~(xviii) the administration of a corticosteroid;~~
~~(xix) the administration of an insulin control medication;~~
~~(xx) the administration of an antipyretic;~~
~~(xxi) the administration of an anti-nausea treatment;~~
~~(xxii) the administration of an anti-diarrheal treatment;~~
~~(xxiii) the administration of N-acetylcysteine; and~~
~~(xxiv) the administration of an antihistamine.~~

~~57~~29. The method of claim 2 wherein the improvement is made by pharmacokinetic/pharmacodynamic monitoring~~, wherein the suboptimally administered drug therapy comprises administration of dianhydrogalactitol, and wherein the preparation of a medicament is for use with pharmacokinetic/pharmacodynamic monitoring~~.

~~58~~30. The method of claim ~~57~~ 29 wherein the pharmacokinetic/pharmacodynamic monitoring is performed by a method selected from the group consisting of:

(i) multiple determinations of blood plasma levels; and
(ii) multiple determinations of at least one metabolite in blood or urine.

~~59. The method of claim 2 wherein the improvement is made by pharmacokinetic/pharmacodynamic monitoring, wherein the suboptimally administered drug therapy comprises administration of diacetyldianhydrogalactitol, and wherein the preparation of a medicament is for use with pharmacokinetic/pharmacodynamic monitoring.~~

~~60. The method of claim 59 wherein the pharmacokinetic/pharmacodynamic monitoring is performed by a method selected from the group consisting of:~~
~~(i) multiple determinations of blood plasma levels; and~~
~~(ii) multiple determinations of at least one metabolite in blood or urine.~~

~~61~~31. The method of claim 2 wherein the improvement is made by drug combination~~, wherein the suboptimally administered drug therapy comprises administration of dianhydrogalactitol, and wherein the preparation of a medicament is for use with a drug combination~~.

~~62~~32. The method of claim ~~61~~31, wherein the drug combination is selected from the group consisting of:

(i) use with topoisomerase inhibitors;
(ii) use with fraudulent nucleosides;
(iii) use with fraudulent nucleotides;
(iv) use with thymidylate synthetase inhibitors;
(v) use with signal transduction inhibitors;
(vi) use with cisplatin or platinum analogs;
(vii) use with alkylating agents;
(viii) use with anti-tubulin agents;
(ix) use with antimetabolites;
(x) use with berberine;
(xi) use with apigenin;
(xii) use with amonafide;
(xiii) use with vinca alkaloids;
(xiv) use with 5-fluorouracil;
(xv) use with curcumin;
(xvi) use with NF-κB inhibitors;
(xvii) use with rosmarinic acid;
(xviii) use with mitoguazone; and
(xix) use with tetrandrine.

~~63~~33. The method of claim ~~62~~32 wherein the drug combination is use with alkylating agents, and the alkylating agent is selected from the group consisting of BCNU, BCNU wafers (Gliadel), and CCNU.

~~64. The method of claim 2 wherein the improvement is made by drug combination, wherein the suboptimally administered drug therapy comprises administration of diacetyldianhydrogalactitol, and wherein the preparation of a medicament is for use with a drug combination.~~

~~65. The method of claim 64, wherein the drug combination is selected from the group consisting of:~~

~~(i) use with topoisomerase inhibitors;~~
~~(ii) use with fraudulent nucleosides;~~
~~(iii) use with fraudulent nucleotides;~~
~~(iv) use with thymidylate synthetase inhibitors;~~
~~(v) use with signal transduction inhibitors;~~
~~(vi) use with cisplatin or platinum analogs;~~
~~(vii) use with alkylating agents;~~
~~(viii) use with anti-tubulin agents;~~
~~(ix) use with antimetabolites;~~
~~(x) use with berberine;~~
~~(xi) use with apigenin;~~
~~(xii) use with amonafide;~~
~~(xiii) use with vinca alkaloids;~~

~~(xiv) use with 5-fluorouracil;~~
~~(xv) use with curcumin;~~
~~(xvi) use with NF-κB inhibitors;~~
~~(xvii) use with rosmarinic acid;~~
~~(xviii) use with mitoguazone; and~~
~~(xix) use with tetrandrine.~~

~~66. The method of claim 65 wherein the drug combination is use with alkylating agents, and the alkylating agent is selected from the group consisting of BCNU, BCNU wafers, and CCNU.~~

~~67~~34. The method of claim 2 wherein the improvement is made by chemosensitization~~, wherein the suboptimally administered drug therapy comprises administration of dianhydrogalactitol, and wherein the preparation of a medicament is for use with chemosensitization~~.

~~68~~35. The method of claim ~~67~~ 34 wherein the chemosensitization comprises the use of dianhydrogalactitol as a chemosensitizer in combination with an agent selected from the group consisting of:

(i) topoisomerase inhibitors;
(ii) fraudulent nucleosides;
(iii) fraudulent nucleotides;
(iv) thymidylate synthetase inhibitors;
(v) signal transduction inhibitors;
(vi) cisplatin or platinum analogs;
(vii) alkylating agents;
(viii) anti-tubulin agents;
(ix) antimetabolites;
(x) berberine;
(xi) apigenin;
(xii) amonafide;
(xiii) vinca alkaloids;
(xiv) 5-fluorouracil;
(xv) curcumin;
(xvi) NF-κB inhibitors;
(xvii) rosmarinic acid;
(xviii) mitoguazone; and
(xix) tetrandrine.

~~69. The method of claim 2 wherein the improvement is made by chemosensitization, wherein the suboptimally administered drug therapy comprises administration of diacetyldianhydrogalactitol, and wherein the preparation of a medicament is for use with chemosensitization.~~

~~70. The method of claim 69 wherein the chemosensitization comprises the use of diacetyldianhydrogalactitol as a chemosensitizer in combination with an agent selected from the group consisting of:~~

~~(i) topoisomerase inhibitors;~~
~~(ii) fraudulent nucleosides;~~
~~(iii) fraudulent nucleotides;~~
~~(iv) thymidylate synthetase inhibitors;~~
~~(v) signal transduction inhibitors;~~
~~(vi) cisplatin or platinum analogs;~~
~~(vii) alkylating agents;~~
~~(viii) anti-tubulin agents;~~
~~(ix) antimetabolites;~~
~~(x) berberine;~~
~~(xi) apigenin;~~
~~(xii) amonafide;~~
~~(xiii) vinca alkaloids;~~
~~(xiv) 5-fluorouracil;~~
~~(xv) curcumin;~~
~~(xvi) NF-κB inhibitors;~~
~~(xvii) rosmarinic acid;~~
~~(xviii) mitoguazone; and~~
~~(xix) tetrandrine.~~

~~71~~36. The method of claim 2 wherein the improvement is made by chemopotentiation~~, wherein the suboptimally administered drug therapy comprises administration of dianhydrogalactitol, and wherein the preparation of a medicament is for use with chemopotentiation~~.

~~72~~37. The method of claim ~~71~~ 36 wherein the ~~chemosensitization~~ chemopotentiation comprises the use of dianhydrogalactitol as a chemopotentiator in combination with an agent selected from the group consisting of:

(i) topoisomerase inhibitors;
(ii) fraudulent nucleosides;
(iii) fraudulent nucleotides;
(iv) thymidylate synthetase inhibitors;
(v) signal transduction inhibitors;
(vi) cisplatin or platinum analogs;
(vii) alkylating agents;
(viii) anti-tubulin agents;
(ix) antimetabolites;
(x) berberine;
(xi) apigenin;
(xii) amonafide;
(xiii) vinca alkaloids;
(xiv) 5-fluorouracil;
(xv) curcumin;
(xvi) NF-κB inhibitors;
(xvii) rosmarinic acid;
(xviii) mitoguazone; and
(xix) tetrandrine.

~~73~~38. The method of claim ~~72~~ 37 wherein the agent is an alkylating agent, and the alkylating agent is selected from the group consisting of:

(i) BCNU;
(ii) BCNU wafers;
(iii) CCNU;
(iv) bendamustine (Treanda); and
(v) temozolomide (Temodar).

~~74. The method of claim 2 wherein the improvement is made by chemopotentiation, wherein the suboptimally administered drug therapy comprises administration of diacetyldianhydrogalactitol, and wherein the preparation of a medicament is for use with chemopotentiation.~~

~~75. The method of claim 74 wherein the chemosensitization comprises the use of diacetyldianhydrogalactitol as a chemosensitizer in combination with an agent selected from the group consisting of:~~

~~(i) topoisomerase inhibitors;~~
~~(ii) fraudulent nucleosides;~~
~~(iii) fraudulent nucleotides;~~
~~(iv) thymidylate synthetase inhibitors;~~
~~(v) signal transduction inhibitors;~~
~~(vi) cisplatin or platinum analogs;~~
~~(vii) alkylating agents;~~
~~(viii) anti-tubulin agents;~~
~~(ix) antimetabolites;~~
~~(x) berberine;~~
~~(xi) apigenin;~~
~~(xii) amonafide;~~
~~(xiii) vinca alkaloids;~~
~~(xiv) 5-fluorouracil;~~
~~(xv) curcumin;~~
~~(xvi) NF-κB inhibitors;~~
~~(xvii) rosmarinic acid;~~
~~(xviii) mitoguazone; and~~
~~(xix) tetrandrine.~~

~~76. The method of claim 75 wherein the agent is an alkylating agent, and the alkylating agent is selected from the group consisting of:~~

~~(i) BCNU;~~
~~(ii) BCNU wafers;~~
~~(iii) CCNU;~~
~~(iv) bendamustine; and~~
~~(v) temozolomide.~~

~~77~~39. The method of claim 2 wherein the improvement is made by post-treatment management~~, wherein the suboptimally administered drug therapy comprises~~

~~administration of dianhydrogalactitol, and wherein the preparation of a medicament is for use with post-treatment management~~.

~~78~~40. The method of claim ~~77~~39 wherein the post-treatment management is selected from the group consisting of:

(i) a therapy associated with pain management;
(ii) administration of an anti-emetic;
(iii) an anti-nausea therapy;
(iv) administration of an anti-inflammatory agent;
(v) administration of an anti-pyretic agent; and
(vi) administration of an immune stimulant.

~~79. The method of claim 2 wherein the improvement is made by post-treatment management, wherein the suboptimally administered drug therapy comprises administration of diacetyldianhydrogalactitol, and wherein the preparation of a medicament is for use with post-treatment management.~~

~~80. The method of claim 79 wherein the post-treatment management is selected from the group consisting of:~~

~~(i) a therapy associated with pain management;~~
~~(ii) administration of an anti-emetic;~~
~~(iii) an anti-nausea therapy;~~
~~(iv) administration of an anti-inflammatory agent;~~
~~(v) administration of an anti-pyretic agent; and~~
~~(vi) administration of an immune stimulant.~~

~~81. The method of claim 2 wherein the improvement is made by alternative medicine/therapeutic support, wherein the suboptimally administered drug therapy comprises administration of dianhydrogalactitol or diacetyldianhydrogalactitol, and wherein the preparation of a medicament is for use with alternative medicine/therapeutic support.~~

~~82. The method of claim 81 wherein the alternative medicine/therapeutic support is selected from the group consisting of:~~

~~(a) hypnosis;~~
~~(b) acupuncture;~~
~~(c) meditation;~~
~~(d) a herbal medication created either synthetically or through extraction; and~~
~~(e) applied kinesiology.~~

~~83~~41. The method of claim ~~82~~2 wherein the improvement is made by alternative medicine/therapeutic support, and wherein the alternative medicine/therapeutic support is a herbal medication created either synthetically or through extraction, and the herbal medication created either synthetically or through extraction is selected from the group consisting of:

(i) a NF-κB inhibitor;
(ii) a natural anti-inflammatory;
(iii) an immunostimulant;

(iv) an antimicrobial; and
(v) a flavonoid, isoflavone, or flavone.

~~84~~42. The method of claim ~~83~~-41 wherein the herbal medication created either synthetically or through extraction is a NF-κB inhibitor, and the NF-κB inhibitor is selected from the group consisting of parthenolide, curcumin, and rosmarinic acid.

~~85~~43. The method of claim ~~83~~-41 wherein the herbal medication created either synthetically or through extraction is a natural anti-inflammatory, and the natural anti-inflammatory is selected from the group consisting of rhein and parthenolide.

~~86~~44. The method of claim ~~83~~-41 wherein the herbal medication created either synthetically or through extraction is an immunostimulant, and the immunostimulant is a product found in or isolated from Echinacea.

~~87~~45. The method of claim ~~83~~-41 wherein the herbal medication created either synthetically or through extraction is an anti-microbial, and the anti-microbial is berberine.

~~88~~46. The method of claim ~~83~~-41 wherein the herbal medication created either synthetically or through extraction is a flavonoid, isoflavone, or flavone, and the flavonoid or flavone is selected from the group consisting of apigenenin, genistein, genistin, 6″-O-malonylgenistin, 6″-O-acetylgenistin, daidzein, daidzin, 6″-O-malonyldaidzin, 6″-O-acetylgenistin, glycitein, glycitin, 6″-O-malonylglycitin, and 6-O-acetylglycitin.

~~89~~47. The method of claim 2 wherein the ~~suboptimally administered drug therapy comprises administration of dianhydrogalactitol, and wherein the preparation of a medicament involves an~~ improvement is made by ~~that is~~ a bulk drug product improvement.

~~90~~48. The method of claim ~~89~~-47 wherein the bulk drug product improvement is selected from the group consisting of:
(i) salt formation;
(ii) preparation as a homogeneous crystal structure;
(iii) preparation as a pure isomer;
(iv) increased purity;
(v) preparation with lower residual solvent content; and
(vi) preparation with lower residual heavy metal content.

~~91. The method of claim 2 wherein the suboptimally administered drug therapy comprises administration of diacetyldianhydrogalactitol, and wherein the preparation of a medicament involves an improvement that is a bulk drug product improvement.~~

~~92. The method of claim 91 wherein the bulk drug product improvement is selected from the group consisting of:~~
~~(i) salt formation;~~
~~(ii) preparation as a homogeneous crystal structure;~~
~~(iii) preparation as a pure isomer;~~
~~(iv) increased purity;~~

~~(v) preparation with lower residual solvent content; and~~
~~(vi) preparation with lower residual heavy metal content.~~

~~93~~49. The method of claim 2 wherein the ~~suboptimally administered drug therapy comprises administration of dianhydrogalactitol, and wherein the preparation of a medicament involves an~~ improvement is made by ~~that is~~ use of a diluent.

~~94~~50. The method of claim ~~93~~ 49 wherein the diluent is selected from the group consisting of:

(i) an emulsion;
(ii) dimethylsulfoxide (DMSO);
(iii) N-methylformamide (NMF);
(iv) DMF;
(v) ethanol;
(vi) benzyl alcohol;
(vii) dextrose-containing water for injection;
(viii) Cremophor;
(ix) cyclodextrin; and
(x) PEG.

~~95. The method of claim 2 wherein the suboptimally administered drug therapy comprises administration of diacetyldianhydrogalactitol, and wherein the preparation of a medicament involves an improvement that is use of a diluent.~~

~~96. The method of claim 95 wherein the diluent is selected from the group consisting of:~~
~~(i) an emulsion;~~
~~(ii) dimethylsulfoxide (DMSO);~~
~~(iii) N-methylformamide (NMF)~~
~~(iv) DMF;~~
~~(v) ethanol;~~
~~(vi) benzyl alcohol;~~
~~(vii) dextrose-containing water for injection;~~
~~(viii) Cremophor;~~
~~(ix) cyclodextrin; and~~
~~(x) PEG.~~

~~97~~51. The method of claim 2 wherein the ~~suboptimally administered drug therapy comprises administration of dianhydrogalactitol, and wherein the preparation of a medicament involves an~~ improvement is made by ~~that is~~ use of a solvent system.

~~98~~52. The method of claim ~~97~~ 51 wherein the solvent system is selected from the group consisting of:

(i) an emulsion;
(ii) dimethylsulfoxide (DMSO);
(iii) N-methylformamide (NMF);
(iv) DMF;

(v) ethanol;
(vi) benzyl alcohol;
(vii) dextrose-containing water for injection;
(viii) Cremophor;
(ix) cyclodextrin; and
(x) PEG.

~~99. The method of claim 2 wherein the suboptimally administered drug therapy comprises administration of diacetyldianhydrogalactitol, and wherein the preparation of a medicament involves an improvement that is use of a solvent system.~~

~~100. The method of claim 99 wherein the solvent system is selected from the group consisting of:~~

~~(i) an emulsion;~~
~~(ii) dimethylsulfoxide (DMSO);~~
~~(iii) N-methylformamide (NMF)~~
~~(iv) DMF;~~
~~(v) ethanol;~~
~~(vi) benzyl alcohol;~~
~~(vii) dextrose-containing water for injection;~~
~~(viii) Cremophor;~~
~~(ix) cyclodextrin; and~~
~~(x) PEG.~~

~~101~~53. The method of claim 2 wherein the ~~suboptimally administered drug therapy comprises administration of dianhydrogalactitol, and wherein the preparation of a medicament involves an~~ improvement is made by ~~that is~~ use of an excipient.

~~102~~54. The method of claim ~~101~~ 53 wherein the excipient is selected from the group consisting of:

(i) mannitol;
(ii) albumin;
(iii) EDTA;
(iv) sodium bisulfite;
(v) benzyl alcohol;
(vi) a carbonate buffer; and
(vii) a phosphate buffer.

~~103. The method of claim 2 wherein the suboptimally administered drug therapy comprises administration of diacetyldianhydrogalactitol, and wherein the preparation of a medicament involves an improvement that is use of an excipient.~~

~~104. The method of claim 103 wherein the excipient is selected from the group consisting of:~~

~~(i) mannitol;~~
~~(ii) albumin;~~
~~(iii) EDTA;~~

~~(iv) sodium bisulfite;~~
~~(v) benzyl alcohol;~~
~~(vi) a carbonate buffer; and~~
~~(vii) a phosphate buffer.~~

~~105~~55. The method of claim 2 wherein the ~~suboptimally administered drug therapy comprises administration of dianhydrogalactitol, and wherein the preparation of a medicament involves an~~ improvement is made by ~~that is~~ use of a dosage form.

~~106~~56. The method of claim ~~105~~ 55 where the dosage form is selected from the group consisting of:

(i) tablets;
(ii) capsules;
(iii) topical gels;
(iv) topical creams;
(v) patches;
(vi) suppositories; and
(vii) lyophilized dosage fills.

~~107. The method of claim 2 wherein the suboptimally administered drug therapy comprises administration of diacetyldianhydrogalactitol, and wherein the preparation of a medicament involves an improvement that is use of a dosage form.~~

~~108. The method of claim 107 where the dosage form is selected from the group consisting of:~~
~~(i) tablets;~~
~~(ii) capsules;~~
~~(iii) topical gels;~~
~~(iv) topical creams;~~
~~(v) patches;~~
~~(vi) suppositories; and~~
~~(vii) lyophilized dosage fills.~~

~~109. The method of claim 2 wherein the suboptimally administered drug therapy comprises administration of dianhydrogalactitol, and wherein the preparation of a medicament involves an improvement that is use of dosage kits and packaging.~~

~~110. The method of claim 109 wherein the dosage kits and packaging are selected from the group consisting of the use of amber vials to protect from light and the use of stoppers with specialized coatings to improve shelf-life stability.~~

~~111. The method of claim 2 wherein the suboptimally administered drug therapy comprises administration of diacetyldianhydrogalactitol, and wherein the preparation of a medicament involves an improvement that is use of dosage kits and packaging.~~

~~112. The method of claim 111 wherein the dosage kits and packaging are selected from the group consisting of the use of amber vials to protect from light and the use of stoppers with specialized coatings to improve shelf-life stability.~~

~~113~~57. The method of claim 2 wherein the ~~suboptimally administered drug therapy comprises administration of dianhydrogalactitol, and wherein the preparation of a medicament involves an~~ improvement is made by ~~that is~~ use of a drug delivery system.

~~114~~58. The method of claim ~~113~~ 57 wherein the drug delivery system is selected from the group consisting of:

(i) nanocrystals;
(ii) bioerodible polymers;
(iii) liposomes;
(iv) slow release injectable gels; and
(v) microspheres.

~~115. The method of claim 2 wherein the suboptimally administered drug therapy comprises administration of diacetyldianhydrogalactitol, and wherein the preparation of a medicament involves an improvement that is use of a drug delivery system.~~

~~116. The method of claim 115 wherein the drug delivery system is selected from the group consisting of:~~

~~(i) nanocrystals;~~
~~(ii) bioerodible polymers;~~
~~(iii) liposomes;~~
~~(iv) slow release injectable gels; and~~
~~(v) microspheres.~~

~~117~~59. The method of claim 2 wherein the ~~suboptimally administered drug therapy comprises administration of dianhydrogalactitol, and wherein the preparation of a medicament involves an~~ improvement is made by ~~that is~~ use of a drug conjugate form.

~~118~~60. The method of claim ~~117~~ 59 wherein the drug conjugate form is selected from the group consisting of:

(i) a polymer system;
(ii) polylactides;
(iii) polyglycolides;
(iv) amino acids;
(v) peptides; and
(vi) multivalent linkers.

~~119~~61. The method of claim ~~118~~ 60 wherein the drug conjugate form is a polymer system, and the polymer system is a polyethylene glycol.

~~120. The method of claim 2 wherein the suboptimally administered drug therapy comprises administration of diacetyldianhydrogalactitol, and wherein the preparation of a medicament involves an improvement that is use of a drug conjugate form.~~

~~121. The method of claim 120 wherein the drug conjugate form is selected from the group consisting of:~~

~~(i) a polymer system;~~
~~(ii) polylactides;~~
~~(iii) polyglycolides;~~
~~(iv) amino acids;~~
~~(v) peptides; and~~
~~(vi) multivalent linkers.~~

~~122. The method of claim 121 wherein the drug conjugate form is a polymer system, and the polymer system is a polyethylene glycol.~~

~~123. The method of claim 2 wherein the suboptimally administered drug therapy comprises administration of dianhydrogalactitol, and wherein the preparation of a medicament involves an improvement that is use of a compound analog.~~

~~124. The method of claim 123 wherein the compound analog is selected from the group consisting of:~~

~~(i) alteration of side chains to increase or decrease lipophilicity;~~
~~(ii) addition of an additional chemical functionality to alter a property selected from the group consisting of reactivity, electron affinity, and binding capacity; and~~
~~(iii) alteration of salt form.~~

~~125. The method of claim 2 wherein the suboptimally administered drug therapy comprises administration of diacetyldianhydrogalactitol, and wherein the preparation of a medicament involves an improvement that is use of a compound analog.~~

~~126. The method of claim 125 wherein the compound analog is selected from the group consisting of:~~

~~(i) alteration of side chains to increase or decrease lipophilicity;~~
~~(ii) addition of an additional chemical functionality to alter a property selected from the group consisting of reactivity, electron affinity, and binding capacity; and~~
~~(iii) alteration of salt form.~~

~~127~~62. The method of claim 2 wherein the ~~suboptimally administered drug therapy comprises administration of dianhydrogalactitol, and wherein the preparation of a medicament involves an~~ improvement is made by ~~that is~~ use of a prodrug system.

~~128~~63. The method of claim ~~127~~ 62 wherein the prodrug system is selected from the group consisting of:

(i) the use of enzyme sensitive esters;
(ii) the use of dimers;
(iii) the use of Schiff bases;
(iv) the use of pyridoxal complexes; and
(v) the use of caffeine complexes.

~~129. The method of claim 2 wherein the suboptimally administered drug therapy comprises administration of diacetyldianhydrogalactitol, and wherein the preparation of a medicament involves an improvement that is use of a prodrug system.~~

~~130. The method of claim 129 wherein the prodrug system is selected from the group consisting of:~~

~~(i) the use of enzyme sensitive esters;~~
~~(ii) the use of dimers;~~
~~(iii) the use of Schiff bases;~~
~~(iv) the use of pyridoxal complexes; and~~
~~(v) the use of caffeine complexes.~~

~~131~~64. The method of claim 2 wherein the ~~suboptimally administered drug therapy comprises administration of dianhydrogalactitol, and wherein the preparation of a medicament involves an~~ improvement is made by ~~that is~~ use of a multiple drug system.

~~132~~65. The method of claim ~~131~~ 64 wherein the multiple drug system employs a mechanism selected from:

(i) use of multi-drug resistance inhibitors;
(ii) use of specific drug resistance inhibitors;
(iii) use of specific inhibitors of selective enzymes;
(iv) use of signal transduction inhibitors;
(v) use of repair inhibition; and
(vi) use of topoisomerase inhibitors with non-overlapping side effects.

~~133. The method of claim 2 wherein the suboptimally administered drug therapy comprises administration of diacetyldianhydrogalactitol, and wherein the preparation of a medicament involves an improvement that is use of a multiple drug system.~~

~~134. The method of claim 132 wherein the multiple drug system employs a mechanism selected from:~~

~~(i) use of multi-drug resistance inhibitors;~~
~~(ii) use of specific drug resistance inhibitors;~~
~~(iii) use of specific inhibitors of selective enzymes;~~
~~(iv) use of signal transduction inhibitors;~~
~~(v) use of repair inhibition; and~~
~~(vi) use of topoisomerase inhibitors with non-overlapping side effects.~~

~~135~~66. The method of claim 2 wherein the ~~suboptimally administered drug therapy comprises administration of dianhydrogalactitol, and wherein the preparation of a medicament involves an~~ improvement is made by ~~that is~~ use of biotherapeutic enhancement.

~~136~~67. The method of claim ~~135~~ 66 wherein the biotherapeutic enhancement is performed by use in combination as sensitizers/potentiators with a therapeutic agent or technique selected from the group consisting of:

(i) cytokines;
(ii) lymphokines;

(iii) therapeutic antibodies;
(iv) antisense therapies;
(v) gene therapies;
(vi) ribozymes; and
(vii) RNA interference.

~~137~~68. The method of claim ~~136~~ 67 wherein the biotherapeutic enhancement is performed by use in combination with a therapeutic antibody, and the therapeutic antibody is selected from the group consisting of bevacizumab (Avastin), rituximab (Rituxan), trastuzumab (Herceptin), and cetuximab (Erbitux).

~~138. The method of claim 2 wherein the suboptimally administered drug therapy comprises administration of diacetyldianhydrogalactitol, and wherein the preparation of a medicament involves an improvement that is use of biotherapeutic enhancement.~~

~~139. The method of claim 138 wherein the biotherapeutic enhancement is performed by use in combination as sensitizers/potentiators with a therapeutic agent or technique selected from the group consisting of:~~
~~(i) cytokines;~~
~~(ii) lymphokines;~~
~~(iii) therapeutic antibodies;~~
~~(iv) antisense therapies;~~
~~(v) gene therapies;~~
~~(vi) ribozymes; and~~
~~(vii) RNA interference.~~

~~140. The method of claim 138 wherein the biotherapeutic enhancement is performed by use in combination with a therapeutic antibody, and the therapeutic antibody is selected from the group consisting of bevacizumab, rituximab, trastuzumab, and cetuximab.~~

~~141~~69. The method of claim 2 wherein the ~~suboptimally administered drug therapy comprises administration of dianhydrogalactitol, and wherein the preparation of a medicament involves an~~ improvement is made by ~~that is~~ use of biotherapeutic resistance modulation.

~~142~~70. The method of claim ~~141~~ 69 wherein the biotherapeutic resistance modulation comprises use against tumors resistant to a therapeutic agent or technique selected from the group consisting of:
(i) biological response modifiers;
(ii) cytokines;
(iii) lymphokines;
(iv) therapeutic antibodies;
(v) antisense therapies;
(vi) gene therapies;
(vii) ribozymes; and
(viii) RNA interference.

~~143~~71. The method of claim ~~142~~ 70 wherein the biotherapeutic resistance modulation comprises use against tumors resistant to a therapeutic antibody, and the therapeutic antibody is selected from the group consisting of bevacizumab (Avastin), rituximab (Rituxan), trastuzumab (Herceptin), and cetuximab (Erbitux).

~~144. The method of claim 2 wherein the suboptimally administered drug therapy comprises administration of diacetyldianhydrogalactitol, and wherein the preparation of a medicament involves an improvement that is use of biotherapeutic resistance modulation.~~

~~145. The method of claim 144 wherein the biotherapeutic resistance modulation comprises use against tumors resistant to a therapeutic agent or technique selected from the group consisting of:~~

~~(i) biological response modifiers;~~
~~(ii) cytokines;~~
~~(iii) lymphokines;~~
~~(iv) therapeutic antibodies;~~
~~(v) antisense therapies;~~
~~(vi) gene therapies;~~
~~(vii) ribozymes; and~~
~~(viii) RNA interference.~~

~~146. The method of claim 145 wherein the biotherapeutic resistance modulation comprises use against tumors resistant to a therapeutic antibody, and the therapeutic antibody is selected from the group consisting of bevacizumab, rituximab, trastuzumab, and cetuximab.~~

~~147~~72. The method of claim 2 wherein the ~~suboptimally administered drug therapy comprises administration of dianhydrogalactitol, and wherein the preparation of a medicament involves an~~ improvement is made by ~~that is~~ use of radiation therapy enhancement.

~~148~~73. The method of claim ~~147~~ 72 wherein the radiation therapy enhancement is performed by use of an agent or technique selected from the group consisting of:

(i) hypoxic cell sensitizers;
(ii) radiation sensitizers/protectors;
(iii) photosensitizers;
(iv) radiation repair inhibitors;
(v) thiol depleters;
(vi) vaso-targeted agents;
(vii) DNA repair inhibitors;
(viii) radioactive seeds;
(ix) radionuclides;
(x) radiolabeled antibodies; and
(xi) brachytherapy.

~~149. The method of claim 2 wherein the suboptimally administered drug therapy comprises administration of diacetyldianhydrogalactitol, and wherein the preparation of a medicament involves an improvement that is use of radiation therapy enhancement.~~

~~150. The method of claim 149 wherein the radiation therapy enhancement is performed by use of an agent or technique selected from the group consisting of:~~

~~(i) hypoxic cell sensitizers;~~
~~(ii) radiation sensitizers/protectors;~~
~~(iii) photosensitizers;~~
~~(iv) radiation repair inhibitors;~~
~~(v) thiol depleters;~~
~~(vi) vaso-targeted agents;~~
~~(vii) DNA repair inhibitors;~~
~~(viii) radioactive seeds;~~
~~(ix) radionuclides;~~
~~(x) radiolabeled antibodies; and~~
~~(xi) brachytherapy.~~

~~151~~74. The method of claim 2 wherein the ~~suboptimally administered drug therapy comprises administration of dianhydrogalactitol, and wherein the preparation of a medicament involves an~~ improvement is made by ~~that is~~ use of a novel mechanism of action.

~~152~~75. The method of claim ~~151~~ 74 wherein the novel mechanism of action is a therapeutic interaction with a target or mechanism selected from the group consisting of:

(i) inhibitors of poly-ADP ribose polymerase;
(ii) agents that affect vasculature or vasodilation;
(iii) oncogenic targeted agents;
(iv) signal transduction inhibitors;
(v) EGFR inhibition;
(vi) protein kinase C inhibition;
(vii) phospholipase C downregulation;
(viii) Jun downregulation;
(ix) histone genes;
(x) VEGF;
(xi) ornithine decarboxylase;
(xii) ubiquitin C;
(xiii) jun D;
(xiv) v-jun;
(xv) GPCRs;
(xvi) protein kinase A;
(xvii) protein kinases other than protein kinase A;
(xviii) prostate specific genes;
(xix) telomerase; and
(xx) histone deacetylase.

~~153. The method of claim 2 wherein the suboptimally administered drug therapy comprises administration of diacetyldianhydrogalactitol, and wherein the preparation of a medicament involves an improvement that is use of a novel mechanism of action.~~

~~154. The method of claim 153 wherein the novel mechanism of action is a therapeutic interaction with a target or mechanism selected from the group consisting of:~~

~~(i) inhibitors of poly-ADP ribose polymerase;~~
~~(ii) agents that affect vasculature or vasodilation;~~
~~(iii) oncogenic targeted agents;~~
~~(iv) signal transduction inhibitors;~~
~~(v) EGFR inhibition;~~
~~(vi) protein kinase C inhibition;~~
~~(vii) phospholipase C downregulation;~~
~~(viii) Jun downregulation;~~
~~(ix) histone genes;~~
~~(x) VEGF;~~
~~(xi) ornithine decarboxylase;~~
~~(xii) ubiquitin C;~~
~~(xiii) jun D;~~
~~(xiv) v-jun;~~
~~(xv) GPCRs;~~
~~(xvi) protein kinase A;~~
~~(xvii) protein kinases other than protein kinase A;~~
~~(xviii) prostate specific genes;~~
~~(xix) telomerase; and~~
~~(xx) histone deacetylase.~~

~~155~~76. The method of claim 2 wherein the ~~suboptimally administered drug therapy comprises administration of dianhydrogalactitol, and wherein the preparation of a medicament involves an~~ improvement is made by ~~that is~~ use of selective target cell population therapeutics.

~~156~~77. The method of claim ~~155~~ 76 wherein the use of selective target cell population therapeutics is a use selected from the group consisting of:

(i) use against radiation sensitive cells;
(ii) use against radiation resistant cells;
(iii) use against energy depleted cells; and
(iv) use against endothelial cells.

~~157. The method of claim 2 wherein the suboptimally administered drug therapy comprises administration of diacetyldianhydrogalactitol, and wherein the preparation of a medicament involves an improvement that is use of selective target cell population therapeutics.~~

~~158. The method of claim 157 wherein the use of selective target cell population therapeutics is a use selected from the group consisting of:~~

~~(i) use against radiation sensitive cells;~~
~~(ii) use against radiation resistant cells;~~
~~(iii) use against energy depleted cells; and~~
~~(iv) use against endothelial cells.~~

~~159~~78. A composition to improve the efficacy and/or reduce the side effects of suboptimally administered drug therapy comprising an alternative selected from the group consisting of:

(a) a therapeutically effective quantity of a modified therapeutic agent or a derivative, analog, or prodrug of a therapeutic agent or modified therapeutic agent, wherein the modified therapeutic agent or the derivative, analog or prodrug of the therapeutic agent or modified therapeutic agent possesses increased therapeutic efficacy or reduced side effects as compared with an unmodified therapeutic agent;

(b) a composition comprising:

(i) a therapeutically effective quantity of a therapeutic agent, a modified therapeutic agent or a derivative, analog, or prodrug of a therapeutic agent or modified therapeutic agent; and

(ii) at least one additional therapeutic agent, therapeutic agent subject to chemosensitization, therapeutic agent subject to chemopotentiation, diluent, excipient, solvent system, or drug delivery system, wherein the composition possesses increased therapeutic efficacy or reduced side effects as compared with an unmodified therapeutic agent;

(c) a therapeutically effective quantity of a therapeutic agent, a modified therapeutic agent, or a derivative, analog, or prodrug of a therapeutic agent or modified therapeutic agent that is incorporated into a dosage form, wherein the therapeutic agent, the modified therapeutic agent, or the derivative, analog, or prodrug of a therapeutic agent or modified therapeutic agent incorporated into the dosage form possesses increased therapeutic efficacy or reduced side effects as compared with an unmodified therapeutic agent; and

(d) a therapeutically effective quantity of a therapeutic agent, a modified therapeutic agent, or a derivative, analog, or prodrug of a therapeutic agent or modified therapeutic agent that is incorporated into a dosage kit and packaging, wherein the therapeutic agent, the modified therapeutic agent, or the derivative, analog, or prodrug of a therapeutic agent or modified therapeutic agent incorporated into the dosage kit and packaging possesses increased therapeutic efficacy or reduced side effects as compared with an unmodified therapeutic agent; ~~and~~

~~(e) a therapeutically effective quantity of a therapeutic agent, a modified therapeutic agent, or a derivative, analog, or prodrug of a therapeutic agent or modified therapeutic agent that is subjected to a bulk drug product improvement, wherein the therapeutic agent, the modified therapeutic agent, or the derivative, analog, or prodrug of a therapeutic agent or modified therapeutic agent subject to the bulk drug product improvement possesses increased therapeutic efficacy or reduced side effects as compared with an unmodified therapeutic agent;~~

wherein the therapeutic agent is dianhydrogalactitol and wherein ~~or~~ the modified therapeutic agent is a modified dianhydrogalactitol~~substituted hexitol~~.

~~160~~79. The composition of claim ~~159~~78 wherein the composition possesses increased efficacy or reduced side effects for cancer therapy.

~~161. The composition of claim 160 wherein the unmodified therapeutic agent is dianhydrogalactitol.~~

~~162. The composition of claim 159 wherein the unmodified therapeutic agent is diacetyldianhydrogalactitol.~~

~~163~~80. The composition of claim ~~159~~ 78 wherein the composition comprises a drug combination comprising:

(a) dianhydrogalactitol; and

(b) an additional therapeutic agent selected from the group consisting of:

(i) topoisomerase inhibitors;
(ii) fraudulent nucleosides;
(iii) fraudulent nucleotides;
(iv) thymidylate synthetase inhibitors;
(v) signal transduction inhibitors;
(vi) cisplatin or platinum analogs;
(vii) alkylating agents;
(viii) anti-tubulin agents;
(ix) antimetabolites;
(x) berberine;
(xi) apigenin;
(xii) amonafide;
(xiii) vinca alkaloids;
(xiv) 5-fluorouracil;
(xv) curcumin;
(xvi) NF-κB inhibitors;
(xvii) rosmarinic acid;
(xviii) mitoguazone; and
(xix) tetrandrine.

~~164~~81. The composition of claim ~~163~~ 80 wherein the additional therapeutic agent is an alkylating agent, and the alkylating agent is selected from the group consisting of BCNU, BCNU wafers, CCNU, bendamustine (Treanda), and temozolomide (Temodar).

~~165. The composition of claim 159 wherein the composition comprises a drug combination comprising:~~

~~(a) diacetyldianhydrogalactitol; and~~

~~(b) an additional therapeutic agent selected from the group consisting of:~~

~~(i) topoisomerase inhibitors;~~
~~(ii) fraudulent nucleosides;~~
~~(iii) fraudulent nucleotides;~~
~~(iv) thymidylate synthetase inhibitors;~~
~~(v) signal transduction inhibitors;~~
~~(vi) cisplatin or platinum analogs;~~
~~(vii) alkylating agents;~~
~~(viii) anti-tubulin agents;~~
~~(ix) antimetabolites;~~
~~(x) berberine;~~
~~(xi) apigenin;~~
~~(xii) amonafide;~~
~~(xiii) vinca alkaloids;~~
~~(xiv) 5-fluorouracil;~~
~~(xv) curcumin;~~

~~(xvi) NF-κB inhibitors;~~
~~(xvii) rosmarinic acid;~~
~~(xviii) mitoguazone; and~~
~~(xix) tetrandrine.~~

~~166. The composition of claim 165 wherein the additional therapeutic agent is an alkylating agent, and the alkylating agent is selected from the group consisting of BCNU, BCNU wafers, CCNU, bendamustine, and temozolomide.~~

~~167~~82. The composition of claim ~~159~~ 78 wherein the composition comprises:

(a) dianhydrogalactitol; and

(b) a therapeutic agent subject to chemosensitization selected from the group consisting of:

(i) topoisomerase inhibitors;
(ii) fraudulent nucleosides;
(iii) fraudulent nucleotides;
(iv) thymidylate synthetase inhibitors;
(v) signal transduction inhibitors;
(vi) cisplatin or platinum analogs;
(vii) alkylating agents;
(viii) anti-tubulin agents;
(ix) antimetabolites;
(x) berberine;
(xi) apigenin;
(xii) amonafide;
(xiii) vinca alkaloids;
(xiv) 5-fluorouracil;
(xv) curcumin;
(xvi) NF-κB inhibitors;
(xvii) rosmarinic acid;
(xviii) mitoguazone; and
(xix) tetrandrine;

wherein the dianhydrogalactitol acts as a chemosensitizer.

~~168. The composition of claim 159 wherein the composition comprises:~~
~~(a) diacetyldianhydrogalactitol; and~~
~~(b) a therapeutic agent subject to chemosensitization selected from the group consisting of:~~
~~(i) topoisomerase inhibitors;~~
~~(ii) fraudulent nucleosides;~~
~~(iii) fraudulent nucleotides;~~
~~(iv) thymidylate synthetase inhibitors;~~
~~(v) signal transduction inhibitors;~~
~~(vi) cisplatin or platinum analogs;~~
~~(vii) alkylating agents;~~
~~(viii) anti-tubulin agents;~~
~~(ix) antimetabolites;~~

~~(x) berberine;~~
~~(xi) apigenin;~~
~~(xii) amonafide;~~
~~(xiii) vinca alkaloids;~~
~~(xiv) 5-fluorouracil;~~
~~(xv) curcumin;~~
~~(xvi) NF-κB inhibitors;~~
~~(xvii) rosmarinic acid;~~
~~(xviii) mitoguazone; and~~
~~(xix) tetrandrine;~~
~~wherein the diacetyldianhydrogalactitol acts as a chemosensitizer.~~

~~169~~83. The composition of claim ~~159~~ 78 wherein the composition comprises:
(a) dianhydrogalactitol; and
(b) a therapeutic agent subject to chemopotentiation selected from the group consisting of:
(i) topoisomerase inhibitors;
(ii) fraudulent nucleosides;
(iii) fraudulent nucleotides;
(iv) thymidylate synthetase inhibitors;
(v) signal transduction inhibitors;
(vi) cisplatin or platinum analogs;
(vii) alkylating agents;
(viii) anti-tubulin agents;
(ix) antimetabolites;
(x) berberine;
(xi) apigenin;
(xii) amonafide;
(xiii) vinca alkaloids;
(xiv) 5-fluorouracil;
(xv) curcumin;
(xvi) NF-κB inhibitors;
(xvii) rosmarinic acid;
(xviii) mitoguazone;
(xix) tetrandrine; and
(xx) biotherapeutics;
wherein the dianhydrogalactitol acts as a chemopotentiator.

~~170~~84. The composition of claim ~~169~~ 83 wherein the additional therapeutic agent is a biotherapeutic and the biotherapeutic is an antibody selected from the group consisting of bevacizumab (Avastin), rituximab (Rituxan), trastuzumab (Herceptin), and cetuximab (Erbitux).

~~171. The composition of claim 159 wherein the composition comprises:~~
~~(a) diacetyldianhydrogalactitol; and~~
~~(b) a therapeutic agent subject to chemopotentiation selected from the group consisting of:~~
~~(i) topoisomerase inhibitors;~~

~~(ii) fraudulent nucleosides;~~
~~(iii) fraudulent nucleotides;~~
~~(iv) thymidylate synthetase inhibitors;~~
~~(v) signal transduction inhibitors;~~
~~(vi) cisplatin or platinum analogs;~~
~~(vii) alkylating agents;~~
~~(viii) anti-tubulin agents;~~
~~(ix) antimetabolites;~~
~~(x) berberine;~~
~~(xi) apigenin;~~
~~(xii) amonafide;~~
~~(xiii) vinca alkaloids;~~
~~(xiv) 5-fluorouracil;~~
~~(xv) curcumin;~~
~~(xvi) NF-κB inhibitors;~~
~~(xvii) rosmarinic acid;~~
~~(xviii) mitoguazone;~~
~~(xix) tetrandrine; and~~
~~(xx) biotherapeutics;~~
~~wherein the diacetyldianhydrogalactitol acts as a chemopotentiator.~~

~~172. The composition of claim 171 wherein the additional therapeutic agent is a biotherapeutic and the biotherapeutic is an antibody selected from the group consisting of bevacizumab, rituximab, trastuzumab, and cetuximab.~~

~~173~~85. The composition of claim ~~159~~ 78 wherein the therapeutic agent is dianhydrogalactitol and the dianhydrogalactitol is subjected to a bulk drug product improvement, wherein the bulk drug product improvement is selected from the group consisting of:

(i) salt formation;
(ii) preparation as a homogeneous crystal structure;
(iii) preparation as a pure isomer;
(iv) increased purity;
(v) preparation with lower residual solvent content; and
(vi) preparation with lower residual heavy metal content.

~~174. The composition of claim 159 wherein the therapeutic agent is diacetyldianhydrogalactitol and the diacetyldianhydrogalactitol is subjected to a bulk drug product improvement, wherein the bulk drug product improvement is selected from the group consisting of:~~
~~(i) salt formation;~~
~~(ii) preparation as a homogeneous crystal structure;~~
~~(iii) preparation as a pure isomer;~~
~~(iv) increased purity;~~
~~(v) preparation with lower residual solvent content; and~~
~~(vi) preparation with lower residual heavy metal content.~~

~~175~~86. The composition of claim ~~159~~ 78 wherein the therapeutic agent is dianhydrogalactitol and the composition comprises a diluent, wherein the diluent is selected from the group consisting of:

(i) an emulsion;
(ii) dimethylsulfoxide (DMSO);
(iii) N-methylformamide (NMF);
(iv) DMF;
(v) ethanol;
(vi) benzyl alcohol;
(vii) dextrose-containing water for injection;
(viii) Cremophor;
(ix) cyclodextrin; and
(x) PEG.

~~176. The composition of claim 159 wherein the therapeutic agent is diacetyldianhydrogalactitol and the composition comprises a diluent, wherein the diluent is selected from the group consisting of:~~

~~(i) an emulsion;~~
~~(ii) dimethylsulfoxide (DMSO);~~
~~(iii) N-methylformamide (NMF)~~
~~(iv) DMF;~~
~~(v) ethanol;~~
~~(vi) benzyl alcohol;~~
~~(vii) dextrose-containing water for injection;~~
~~(viii) Cremophor;~~
~~(ix) cyclodextrin; and~~
~~(x) PEG.~~

~~177~~87. The composition of claim ~~159~~ 78 wherein the therapeutic agent is dianhydrogalactitol and the composition comprises a solvent system, wherein the solvent system is selected from the group consisting of:

(i) an emulsion;
(ii) dimethylsulfoxide (DMSO);
(iii) N-methylformamide (NMF);
(iv) DMF;
(v) ethanol;
(vi) benzyl alcohol;
(vii) dextrose-containing water for injection;
(viii) Cremophor;
(ix) cyclodextrin; and
(x) PEG.

~~178. The composition of claim 159 wherein the therapeutic agent is diacetyldianhydrogalactitol and the composition comprises a solvent system, wherein the solvent system is selected from the group consisting of:~~

~~(i) an emulsion;~~
~~(ii) dimethylsulfoxide (DMSO);~~

~~(iii) N-methylformamide (NMF)~~
~~(iv) DMF;~~
~~(v) ethanol;~~
~~(vi) benzyl alcohol;~~
~~(vii) dextrose-containing water for injection;~~
~~(viii) Cremophor;~~
~~(ix) cyclodextrin; and~~
~~(x) PEG.~~

~~179~~88. The composition of claim ~~159~~ 78 wherein the therapeutic agent is dianhydrogalactitol and the composition comprises an excipient, wherein the excipient is selected from the group consisting of:

(i) mannitol;
(ii) albumin;
(iii) EDTA;
(iv) sodium bisulfite;
(v) benzyl alcohol;
(vi) a carbonate buffer; and
(vii) a phosphate buffer.

~~180. The composition of claim 159 wherein the therapeutic agent is diacetyldianhydrogalactitol and the composition comprises an excipient, wherein the excipient is selected from the group consisting of:~~
~~(i) mannitol;~~
~~(ii) albumin;~~
~~(iii) EDTA;~~
~~(iv) sodium bisulfite;~~
~~(v) benzyl alcohol;~~
~~(vi) a carbonate buffer; and~~
~~(vii) a phosphate buffer.~~

~~181~~89. The composition of claim ~~159~~ 78 wherein the therapeutic agent is dianhydrogalactitol and the dianhydrogalactitol is incorporated into a dosage form selected from the group consisting of:

(i) tablets;
(ii) capsules;
(iii) topical gels;
(iv) topical creams;
(v) patches;
(vi) suppositories; and
(vii) lyophilized dosage fills.

~~182. The composition of claim 159 wherein the therapeutic agent is diacetyldianhydrogalactitol and the diacetyldianhydrogalactitol is incorporated into a dosage form selected from the group consisting of:~~
~~(i) tablets;~~
~~(ii) capsules;~~

~~(iii) topical gels;~~
~~(iv) topical creams;~~
~~(v) patches;~~
~~(vi) suppositories; and~~
~~(vii) lyophilized dosage fills.~~

~~183. The composition of claim 159 wherein the therapeutic agent is dianhydrogalactitol and the dianhydrogalactitol is incorporated into a dosage kit and packaging selected from the group consisting of amber vials to protect from light and stoppers with specialized coatings to improve shelf-life stability.~~

~~184. The composition of claim 159 wherein the therapeutic agent is diacetyldianhydrogalactitol and the diacetyldianhydrogalactitol is incorporated into a dosage kit and packaging selected from the group consisting of amber vials to protect from light and stoppers with specialized coatings to improve shelf-life stability.~~

~~185~~90. The composition of claim ~~159~~ 78 wherein the therapeutic agent is dianhydrogalactitol and the composition comprises a drug delivery system selected from the group consisting of:

(i) nanocrystals;
(ii) bioerodible polymers;
(iii) liposomes;
(iv) slow release injectable gels; and
(v) microspheres.

~~186. The composition of claim 159 wherein the therapeutic agent is diacetyldianhydrogalactitol and the composition comprises a drug delivery system selected from the group consisting of:~~
~~(i) nanocrystals;~~
~~(ii) bioerodible polymers;~~
~~(iii) liposomes;~~
~~(iv) slow release injectable gels; and~~
~~(v) microspheres.~~

~~187~~91. The composition of claim ~~159~~ 78 wherein the therapeutic agent is dianhydrogalactitol and the dianhydrogalactitol is present in the composition in a drug conjugate form selected from the group consisting of:

(i) a polymer system;
(ii) polylactides;
(iii) polyglycolides;
(iv) amino acids;
(v) peptides; and
(vi) multivalent linkers.

~~188. The composition of claim 159 wherein the therapeutic agent is diacetyldianhydrogalactitol and the diacetyldianhydrogalactitol is present in the composition in a drug conjugate form selected from the group consisting of:~~

~~(i) a polymer system;~~
~~(ii) polylactides;~~
~~(iii) polyglycolides;~~
~~(iv) amino acids;~~
~~(v) peptides; and~~
~~(vi) multivalent linkers.~~

~~189. The composition of claim 159 wherein the therapeutic agent is a modified dianhydrogalactitol and the modification is selected from the group consisting of:~~
~~(i) alteration of side chains to increase or decrease lipophilicity;~~
~~(ii) addition of an additional chemical functionality to alter a property selected from the group consisting of reactivity, electron affinity, and binding capacity; and~~
~~(iii) alteration of salt form.~~

~~190. The composition of claim 159 wherein the therapeutic agent is a modified diacetyldianhydrogalactitol and the modification is selected from the group consisting of:~~
~~(i) alteration of side chains to increase or decrease lipophilicity;~~
~~(ii) addition of an additional chemical functionality to alter a property selected from the group consisting of reactivity, electron affinity, and binding capacity; and~~
~~(iii) alteration of salt form.~~

~~191~~92. The composition of claim ~~159~~ 78 wherein the therapeutic agent is dianhydrogalactitol and the dianhydrogalactitol is in the form of a prodrug system, wherein the prodrug system is selected from the group consisting of:
(i) the use of enzyme sensitive esters;
(ii) the use of dimers;
(iii) the use of Schiff bases;
(iv) the use of pyridoxal complexes; and
(v) the use of caffeine complexes.

~~192. The composition of claim 159 wherein the therapeutic agent is diacetyldianhydrogalactitol and the diacetyldianhydrogalactitol is in the form of a prodrug system, wherein the prodrug system is selected from the group consisting of:~~
~~(i) the use of enzyme sensitive esters;~~
~~(ii) the use of dimers;~~
~~(iii) the use of Schiff bases;~~
~~(iv) the use of pyridoxal complexes; and~~
~~(v) the use of caffeine complexes.~~

~~193~~93. The composition of claim ~~159~~ 78 wherein the therapeutic agent is dianhydrogalactitol and the composition further comprises at least one additional therapeutic agent to form a multiple drug system, wherein the at least one additional therapeutic agent is selected from the group consisting of:
(i) an inhibitor of multi-drug resistance;
(ii) a specific drug resistance inhibitor;
(iii) a specific inhibitor of a selective enzyme;
(iv) a signal transduction inhibitor;

(v) an inhibitor of a repair enzyme; and
(vi) a topoisomerase inhibitor with non-overlapping side effects.

~~194. The composition of claim 159 wherein the therapeutic agent is diacetyldianhydrogalactitol and the composition further comprises at least one additional therapeutic agent to form a multiple drug system, wherein the at least one additional therapeutic agent is selected from the group consisting of:~~

~~(i) an inhibitor of multi-drug resistance;~~
~~(ii) a specific drug resistance inhibitor;~~
~~(iii) a specific inhibitor of a selective enzyme;~~
~~(iv) a signal transduction inhibitor;~~
~~(v) an inhibitor of a repair enzyme; and~~
~~(vi) a topoisomerase inhibitor with non-overlapping side effects.~~